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October 17, 1997

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WASHINGTON, DC

WHEN: November 18, 1997 at 9:00 am.
WHERE: Office of the Federal Register
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800 North Capitol Street, NW
Washington, DC
(3 blocks north of Union Station Metro)
RESERVATIONS: 202–523–4538

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DEPARTMENT OF AGRICULTURE

Commodity Credit Corporation

7 CFR Part 1437

RIN 0560–AF23

Noninsured Crop Disaster Assistance Program

AGENCY: Commodity Credit Corporation, USDA.

ACTION: Interim rule.

SUMMARY: This interim rule includes provisions for providing assistance under the Noninsured Crop Disaster Assistance Program (NAP) for: aquacultural species; floriculture; forage; ornamental nursery; seed crops; reseeding or replanting of the same crop; and value loss crops. Amendments include redefining some existing terms and adding new terms and changes of applicability, eligibility, assistance, yield determinations, acreage and production reports, loss requirements, and payments for reduced yields and prevented planting.

EFFECTIVE DATE: October 17, 1997.

FOR FURTHER INFORMATION CONTACT: Sean O'Neill, Chief, Noninsured Assistance Branch (NAB), Production, Emergencies, and Compliance Division (PECD), Farm Service Agency (FSA), United States Department of Agriculture, STOP 0526, 1400 Independence Avenue, SW, Washington, D.C. 20250–0526; telephone (202) 720–9003.

SUPPLEMENTARY INFORMATION:

Executive Order 12866

This proposed rule is issued in conformance with Executive Order 12866 and has been determined to be not significant and therefore has not been reviewed by OMB.

Regulatory Flexibility Act

It has been determined that the Regulatory Flexibility Act is not applicable to this rule because neither FSA nor the CCC is required by 5 U.S.C. 553 or any other provision of law to publish a notice of proposed rulemaking with respect to the subject matter of this rule.

Environmental Evaluation

It has been determined by an environmental evaluation that this action will have no significant impact on the quality of the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is needed.

Executive Order 12988

The proposed rule has been reviewed in accordance with Executive Order 12988. The provisions of this proposed rule preempt State laws to the extent such laws are inconsistent with the provisions of this rule. Before any judicial action may be brought concerning the provisions of this rule, the administrative remedies must be exhausted.

Executive Order 12372

This program is not subject to the provisions of Executive Order 12372, which require intergovernmental consultation with State and local officials. See the Notice related to 7 CFR part 3015, subpart V, published at 48 FR 29115 (June 24, 1983).

Unfunded Mandates

This rule contains no Federal mandates under the regulatory provisions of Title II of the (UMRA) for State, local, and tribal governments or the private sector. Thus, this rule is not subject to the requirements of sections 202 and 205 of the UMRA regulations.

Paperwork Reduction Act

Title: Noninsured Crop Disaster Assistance Program.

OMB Control Number: 0560–0175.

Expiration Date: May 31, 1998.

Type of Request: Extension and revision of a currently approved information collection.

Abstract: The information collected under OMB control number 0560–0175, as identified above, allows CCC to effectively administer noninsured crop disaster assistance authorized by the Federal Agriculture Improvement and Reform Act of 1996. The information collected allows CCC to provide assistance under the noninsured crop disaster assistance program for losses of commercial crops or other agricultural commodities that are produced for food or fiber. The information collected is necessary to provide those charged with determining eligibility for CCC a basis to determine whether the producer meets applicable conditions for assistance and to determine compliance with existing rules.

Estimate of Burden: Public reporting burden for this information collection is estimated to average .2 hours per response.

Respondents: Commercial agricultural producers of food or fiber.

Estimated Number of Respondents: 1,575,000.

Estimated Number of Responses per Respondent: 5.

Estimated Total Annual Burden on Respondents: 1,711,250 hours.

Proposed topics for comment include: (a) Whether the continued collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the CCC's estimate of burden including the validity of the methodology and assumptions used; (c) enhancing the quality, utility, and clarity of the information collected; or (d) minimizing the burden of the collection of the information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology. Comments should be sent to the Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, D.C. 20503, and to Sean O'Neill, Chief, Noninsured Assistance Branch (NAB), Production, Emergencies, and Compliance Division (PECD), Farm Service Agency (FSA), United States Department of Agriculture, STOP 0526, 1400 Independence Avenue, SW, Washington, D.C. 20250–0526. All comments will become a matter of public record.

OMB is required to make a decision concerning the collection(s) of information contained in these proposed regulations between 30 and 60

days after publication of this document in the **Federal Register**. Therefore, a comment to OMB is best assured of having its full effect if OMB receives it within 30 days of publication.

Executive Order 12612

It has been determined that this rule does not have sufficient Federalism implications to warrant the preparation of a Federalism Assessment. The provisions contained in this rule will not have a substantial direct effect on States or their political subdivisions, or on the distribution of power and responsibilities among the various levels of Government.

Federal Assistance Programs

This program is listed in the Catalog of Federal Domestic Assistance under No. 10.450.

Background

The regulation reflects changes in existing definitions, additional definitions, eligibility, assistance, yield determinations, acreage and production reporting requirements, loss requirements, and payments for reduced yields and prevented planting. Major changes include:

(1) Section 1437.4 is amended to specify that except for ornamental nursery and species or types and varieties of forage determined by CCC to be predominantly grazed, different species or types and varieties may be treated as separate crops.

(2) Section 1437.5 is amended to include a method for CCC to establish the value of an animal unit day.

(3) Section 1437.7 is amended to specify that CCC will establish expected area yields, or an equivalent measure in the event yield data are not available.

(4) Section 1437.8 is amended to include that, for forage, acreage reports must include the species or type and variety of forage reported, and the intended harvest method, i.e. grazing or mechanically harvested.

(5) Section 1437.9 is amended to require reseeding or replanting where it is practicable.

(6) Section 1437.11 is amended to include payments for losses of forage determined by CCC to be predominantly grazed.

List of Subjects in 7 CFR Part 1437

Agricultural commodities, Disaster assistance, Reporting and recordkeeping requirements.

For the reasons set out in the Preamble, 7 CFR Chapter XIV is amended as set forth below.

PART 1437—NONINSURED CROP DISASTER ASSISTANCE PROGRAM REGULATIONS FOR THE 1997 AND SUCCEEDING CROP YEARS

1. The authority citation continues to read as follows:

Authority: 15 U.S.C. 714b and 714c and 7 U.S.C. 7333.

1a. Revise the heading for part 1437 to read as set forth above.

2. Revise § 1437.1 to read as follows:

§ 1437.1 Applicability.

(a) For the 1997 and subsequent crop years, NAP is intended to provide eligible producers of eligible crops with protection comparable to the catastrophic risk protection plan of crop insurance. NAP is also designed to help reduce production risks faced by producers of crops for which Federal crop insurance under the Federal Crop Insurance Act, as amended is not available. NAP will reduce financial losses that occur when natural disasters cause a catastrophic loss of production or prevented planting of an eligible crop. Payment eligibility is based on an expected yield for the area and the producer's approved yield based on actual production history, or a transitional yield if sufficient production records are not available. In the case of forage determined by CCC to be predominantly grazed in accordance with § 1437.7(j), payment eligibility is based on an expected stocking level for the area and unit and the actual number of animals grazed and days grazing occurred. Production for both the applicable area expected yield and the individual producer approved yield for the unit or for forage determined by CCC to be predominantly grazed, area and unit expected stocking level must each fall below specified percentages in order to be eligible for payments under this part.

(b) The provisions contained in this part are applicable to each eligible producer and each eligible crop for which catastrophic coverage is not otherwise available.

3. Amend § 1437.3 to add new definitions for Animal unit, Animal unit day, Carrying Capacity, Floriculture, Grazing days, Ornamental Nursery, Stocking rate, Type and weight range, and Value loss crop, in alphabetical order, and revise existing definitions for Aquacultural species, Average market price, Eligible crop, Forage, Harvested, and Unit to read as follows:

§ 1437.3 Definitions.

* * * * *

Animal unit (AU) means an animal with daily energy requirement equating to 15.7 pounds of corn.

Animal unit day (AUD) means an expression of an expected or actual stocking rate.

* * * * *

Aquacultural species means any species of aquatic organism grown as food for human consumption, or fish raised as feed for fish that are consumed by humans, or ornamental fish propagated and reared in an aquatic medium by a commercial operator on private property in water in a controlled environment. Eligible aquacultural species must be seeded in the aquacultural facility and not be growing naturally in the facility and must be planted or seeded in containers, wire baskets, net pens, or similar devices designed for the protection and containment of the seeded aquacultural species.

* * * * *

Average market price means the price, or dollar equivalent on an appropriate basis for an eligible crop established by CCC for determining payment amounts under NAP; for example, pound, bushel, ton, and AUD (for forage determined by CCC to be predominantly grazed). Such price will be on a harvested basis without the inclusion of transportation, storage, processing, packing, marketing or other post-harvest expenses and will be based, in part, on historical data.

Carrying Capacity means the stocking rate, as determined by CCC, expressed as acres per animal unit (AC/AU) or reciprocal, which is consistent with maintaining or improving vegetation or related resources.

* * * * *

Eligible crop means an agricultural commodity for which catastrophic coverage is not available and which is commercially produced for food or fiber as specified in this part. Eligible crop will also include floriculture, ornamental nursery, and Christmas tree crops, turfgrass sod, seed crops, aquaculture (including ornamental fish), and industrial crops. In the case of a crop that historically has multiple plantings in the same crop year that are planted or are prevented from being planted, each planting may be considered a different crop for determining payments under this part as determined by CCC. In the case of a crop, except for forage determined by CCC to be predominantly grazed, that has different varieties or types, each variety or type may be considered a separate crop for determining payments under this part, if CCC determines there

is a significant difference in price or yield between the varieties or types.

* * * * *

Floriculture means cut flowers or similar products of annual and perennial flowering plants grown under glass, fiberglass and other rigid plastics, film plastic, shade cloth, natural shade, other shade, and outdoor in a container or controlled environment for commercial sale.

Forage means land covered with grass or other similar herbaceous vegetation not of a woody plant species, produced under such range management practices as are necessary to sustain sufficient quality and quantity of grass or similar vegetation each year to be suitable for grazing or mechanical harvest to feed livestock in a commercial operation. NAP benefits for forage produced on Federal or State owned lands are available only for seeded forage.

* * * * *

Grazing days means the number of days used in the calculation of the carrying capacity for each forage species or type or variety determined by CCC to be predominantly grazed.

Harvested means a single harvest crop is considered harvested when the producer has, by hand or mechanically, or by grazing of livestock, removed the crop from the field. Crops with multiple harvests in 1 year or harvested over multiple years are considered harvested when the producer has, by hand or mechanically removed at least one mature crop from the field. The mechanically harvested crop is considered harvested once it is removed from the field and placed in a truck or other conveyance, except hay is considered harvested when in the bale, whether removed from the field or not. Grazing is not considered harvesting for the purpose of determining an unharvested or prevented planting payment factor.

* * * * *

Ornamental Nursery means decorative plants grown in a container or controlled environment for commercial sale.

* * * * *

Stocking rate means the number of animal units grazing or utilizing specific crop acreage for a specific number of days, expressed as animal unit days.

Type and weight range means the identification of animals according to the daily energy requirement, as determined by CCC, necessary to provide the daily maintenance ration, as determined by CCC, of the specific animal.

* * * * *

Unit means, for NAP, all acreage of the eligible crop or for ornamental nursery, all eligible plant species and sizes except plant species or sizes for which catastrophic coverage is available, in the county for the crop year:

(1) In which the person has 100 percent crop share; or

(2) Which is owned by one person and operated by another person on a share basis.

Value loss crop means ornamental nursery, Christmas trees, aquaculture, or other crops as determined by CCC that, due to their unique nature do not lend themselves to yield calculations or expected yield loss situations. Eligibility for a crop categorized as value loss shall be determined based on a loss of value at time of disaster, as determined by CCC.

4. Amend § 1437.4 to revise the second sentence of paragraph (a) and paragraph (b)(10) to read as follows:

§ 1437.4 Eligibility.

(a) * * * Except for ornamental nursery and species or type or variety of a species of forage determined by CCC to be predominantly grazed, different types or varieties of a crop or commodity, may be treated as a separate eligible crop, if CCC determines there is a significant difference in price or yield.

(b) * * *

(10) Seed crops, where the propagation stock is commercially produced for sale as seed stock for other eligible NAP crop production; and

* * * * *

5. In § 1437.5 add paragraph (f) to read as follows:

§ 1437.5 Assistance.

* * * * *

(f) Animal Unit Day value will be established by CCC on the basis of a 5 year national average corn price per pound, as determined by CCC, and the daily energy requirement of one beef cow, as determined by CCC.

6. Amend § 1437.7 to revise the first sentence of paragraph (a) and add paragraphs (k) and (l) to read as follows:

§ 1437.7 Yield determinations.

(a) CCC will establish expected area yields or an equivalent measure in the event yield data are not available, for eligible crops for each county or area for which the NAP is available, using available information, which may include, but is not limited to, National Agricultural Statistics Service data, Cooperative State Research, Education, and Extension Service records, Federal Crop Insurance Corporation data, credible nongovernment studies, yields in similar areas, and reported approved yield data. * * *

* * * * *

(k) Prior to the beginning of the crop year, CCC in its own discretion will with respect to forage:

(1) Identify each species or type and variety of forage found in the county;

(2) Categorize each species or type and variety of forage identified as either:

(i) Predominantly mechanical harvested, or

(ii) Predominantly grazed;

(3) Establish a carrying capacity for each forage species or type and variety identified and determined by CCC to be predominantly grazed;

(4) Determine total acreage of forage determined by CCC to be predominantly grazed; and

(5) Calculate expected Animal Unit Day by dividing the total acres of forage in the county categorized by CCC as predominantly grazed by the approved carrying capacity and multiplying the result by the number of days of grazing used to determine the carrying capacity.

(l) In the event CCC receives a notice of loss of forage determined by CCC to be predominantly grazed, CCC will:

(1) Calculate utilized Animal Unit Day by dividing the total acres of forage reported to FSA determined by CCC to be predominantly grazed by the reported number of animal units grazed and multiplying the result by the number of days grazing occurred;

(2) Subtract the value of supplemental feed fed to the grazing livestock during the grazing period from the value of the utilized Animal Unit Day, as determined by CCC;

(3) Determine area utilization by dividing total area utilized Animal Unit Day by the expected Animal Unit Day; and

(4) Determine unit utilization by dividing the unit utilized Animal Unit Day by the expected unit Animal Unit Day.

7. Amend § 1437.8 to revise paragraph (b)(4) and add paragraphs (e) and (f) to read as follows:

§ 1437.8 Acreage and production reports.

* * * * *

(b) * * *

(4) The crop, practice, intended use, and for forage, the predominant species or type and variety and the intended harvest method, i.e. grazing or mechanical harvest.

* * * * *

(e) In lieu of a production report, producers of forage that is predominantly grazed shall, in the crop year in which the producer files a notice of loss, report grazing animals by type

and weight range and the number of days grazing occurred, and the amount and type of feed fed such grazing animals during any grazing period within the crop year.

(f) Animal Unit Day adjustments, as determined by CCC, may be calculated when a producer of forage predominantly grazed, provides adequate evidence, as determined by CCC, that unit forage management and maintenance practices provide different carrying capacity than practices generally provided forage acreage used to calculate the approved county expected carrying capacity.

8. Amend § 1437.9 to revise paragraph (b)(2) to read as follows:

§ 1437.9 Loss Requirements.

* * * * *

(b) * * *

(2) The failure of the producer to reseed or replant to the same crop in the county where it is practicable to reseed or replant;

* * * * *

9. Amend § 1437.11 to revise the introductory text and add paragraph (c) to read as follows:

§ 1437.11 Payments for reduced yields and prevented planting.

In the event that the area loss requirement has been satisfied for the crop and:

* * * * *

(c) The producer has sustained a loss of forage determined by CCC to be predominantly grazed in accordance with § 1437.7(l), in excess of 50 percent of the producer's expected Animal Unit Day established for the unit, the NAP payment will be determined by:

(1) Dividing the unit acreage for each species or type or variety identified on the unit by the approved carrying capacity and multiplying the result by the corresponding grazing days used as the basis for determination of the carrying capacity, totaling the result for each species or types and varieties.

(2) Multiplying the result of paragraph (c)(1) of this section by 50 percent.

(3) Multiplying the number of animals grazed by the daily allowance of corn according to type and weight range and divide the result by pounds of corn CCC determines is necessary to provide the daily energy requirement for one animal unit.

(4) Multiplying the result of paragraph (c)(3) of this section by the number of days grazing occurred to determine gross actual AUD.

(5) Adding AUD for ineligible causes of loss and incidental mechanically harvested Category 1 forage to the result of paragraph (c)(4) of this section.

(6) Subtracting AUD or equivalent value of supplemental feed fed to the grazing livestock during the crop year from the result of paragraph (c)(5) of this section.

(7) Subtracting the result of paragraph (c)(6) of this section from the result of paragraph (c)(2) of this section. If a zero or negative number results, payment cannot be calculated.

(8) Multiplying the positive result of paragraph (c)(7) of this section by:

(i) For the 1997 through 1998 crop years, 60 percent of the average market price, as determined by CCC, or any comparable coverage, as determined by CCC; or

(ii) For the 1999 and subsequent years, 55 percent of the average market price, as determined by CCC, or any comparable coverage, as determined by CCC.

Signed at Washington, DC, on October 8, 1997.

Keith Kelly,

Executive Vice President, Commodity Credit Corporation.

[FR Doc. 97–27432 Filed 10–16–97; 8:45 am]

BILLING CODE 3410–01–P

NUCLEAR REGULATORY COMMISSION

10 CFR Part 50

RIN 3150–AF73

Codes and Standards; IEEE National Consensus Standard

AGENCY: Nuclear Regulatory Commission.

ACTION: Direct final rule.

SUMMARY: The Nuclear Regulatory Commission is amending its regulations to incorporate by reference IEEE Std. 603–1991, a national consensus standard for power, instrumentation, and control portions of safety systems in nuclear power plants. This action is necessary to endorse the latest version of this national consensus standard in NRC's regulations, and replace an IEEE standard currently endorsed in the NRC's regulations which has been withdrawn by the IEEE.

EFFECTIVE DATE: The final rule is effective on January 1, 1998, unless significant adverse comments are received by December 1, 1997. If the effective date is delayed, timely notice will be published in the **Federal Register**. The incorporation by reference of IEEE Std. 603–1991 is approved by the Director of the Federal Register as of January 1, 1998.

ADDRESSES: Mail comments to: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; Attention: Rulemakings and Adjudications Staff. Hand deliver comments to 11555 Rockville Pike, Rockville, Maryland, between 7:30 a.m. and 4:15 p.m. on Federal workdays.

FOR FURTHER INFORMATION CONTACT: Satish K. Aggarwal, Senior Program Manager, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Telephone (301) 415–6005, Fax (301) 415–5074 (e-mail: SKA@NRC.GOV).

SUPPLEMENTARY INFORMATION: NRC considers this rulemaking, which endorses IEEE Std. 603–1991, to be noncontroversial because, as noted in the background discussion, there was no adverse public comment on the regulatory guide endorsing this standard. Accordingly, the Commission finds that public notice and opportunity for comment are unnecessary pursuant to 5 U.S.C. 553(b)(B). Thus, the Commission is publishing this rule in final form without seeking public comments on the amendment in a proposed rule. This action will become effective on January 1, 1998. However, if the NRC receives significant adverse comments by December 1, 1997, then the NRC will publish a document that withdraws this action, and will address the comments received in response to an identical proposed rule which is being concurrently published in the proposed rules section of this **Federal Register**. Any significant adverse comments will be addressed in a subsequent final rule. The NRC will not initiate a second comment period on this action in the event the direct final rule is withdrawn.

Background

In 10 CFR part 50, ''Domestic Licensing of Production and Utilization Facilities,'' § 50.55a requires that the protection systems in nuclear power plants meet the requirements set forth in IEEE Std. 279, ''Criteria for Protection Systems for Nuclear Power Generating Stations,'' in effect on the formal docket date of the application. However, IEEE Std. 279 is obsolete, has been withdrawn by IEEE and has now been superseded by IEEE Std. 603–1991, ''Criteria for Safety Systems for Nuclear Power Generating Stations.''

In November 1995, the NRC staff issued for public comment a draft regulatory guide, DG–1042, which was proposed Revision 1 to Regulatory Guide 1.153, ''Criteria for Safety Systems.'' This draft regulatory guide proposed to endorse IEEE Std. 603–1991

(including the correction sheet dated January 30, 1995). Because there were no adverse public comments to Revision 1 to Regulatory Guide 1.153, the Commission believes that there is general public consensus that IEEE Std. 603–1991 provides acceptable criteria for safety systems in nuclear power plants.

Discussion

The direct final rule incorporates a national consensus standard, IEEE Std. 603–1991, for establishing minimal functional and design requirements for power, instrumentation, and control portions of safety systems for nuclear power plants into NRC regulations. This action is consistent with the provisions of the National Technology Transfer and Advancement Act of 1995, Pub. L. 104–113, which encourages Federal regulatory agencies to consider adopting industry consensus standards as an alternative to de novo agency development of standards affecting an industry. This action is also consistent with the NRC policy of evaluating the latest versions of national consensus standards in terms of their suitability for endorsement by regulations or regulatory guides.

Currently, 10 CFR 50.55 a(h) specifies that ''protection systems'' for plants with construction permits issued after January 1, 1971, must meet the requirements in IEEE Std. 279 in effect on the formal docket date of the application for a construction permit. IEEE Std. 279 states that a ''protection system'' encompasses all electric and mechanical devices and circuitry (from sensors to actuation device input terminals) involved in generating those signals associated with the protective function. These signals include those that actuate reactor trip and that, in the event of a serious reactor accident, actuate engineered safeguards such as containment isolation, core spray, safety injection, pressure reduction, and air cleaning. ''Protective Function'' is defined by IEEE Std. 279, as ''the sensing of one or more variables associated with a particular generating station condition, signal processing, and the initiation and completion of the protective action at values of the variables established in the design bases.''

IEEE Std. 603–1991 uses the term ''safety systems'' rather than ''protection systems.'' A ''safety system'' is defined by IEEE Std. 603–1991 as ''a system that is relied upon to remain functional during and following design basis events to ensure: (i) The integrity of the reactor coolant pressure boundary, (ii) the capability to shut down the reactor and maintain it in a safe shut down condition, or (iii) the capability to prevent or mitigate the consequences of accidents that could result in potential off-site exposures comparable to the 10 CFR part 100 guidelines.'' A ''safety function'' is defined by IEEE Std. 603–1991 as ''one of the processes or conditions (for example, emergency negative reactivity insertion, post-accident heat removal, emergency core cooling, post-accident radioactivity removal, and containment isolation) essential to maintain plant parameters within acceptable limits established for a design basis event.''

The Commission considers that the systems covered by IEEE Std. 603–1991 and IEEE Std. 279–1971 are the same. Therefore, for purposes of paragraph (h) of 10 CFR 50.55a, ''protection systems,'' and ''safety systems'' are synonymous. The Commission notes that these two terms are also synonymous with the term ''safety-related systems,'' used elsewhere in the Commission's regulations. Therefore, licensees are expected to apply IEEE Std. 279–1971 and IEEE Std. 603–1991, as appropriate, to ''safety-related systems.''

This rule mandates the use of IEEE Std. 603–1991 (including the correction sheet dated January 30, 1995) for future nuclear power plants, including final design approvals, design certifications and combined licenses under 10 CFR part 52. Current licensees may continue to meet the requirements set forth in the edition or revision of IEEE Std. 279 in effect on the formal date of their application for a construction permit or may, at their option, use IEEE Std. 603–1991, provided they comply with all applicable requirements for making changes to their licensing basis. However, changes to protection systems in operating nuclear power plants initiated on or after January 1, 1998 must meet the requirements in IEEE Std. 603–1991. For purposes of this rule, ''changes'' to protection systems include (i) modifications, augmentation or replacement of protection systems permitted by license amendments, (ii) changes made by the licensees pursuant to procedures in 10 CFR 50.59, and (iii) plant-specific departures from a design certification rule under 10 CFR part 52. In-kind (like-for-like) replacement of protection system components are not considered changes to the protection systems.

Section 3 of IEEE Std. 603–1991 references several industry codes and standards. If the referenced standard has been endorsed in a regulatory guide, the standard constitutes a method acceptable to the Commission of meeting a regulatory requirement as described in the regulatory guide. If a referenced standard has not been endorsed in a regulatory guide, the licensees and applicants may consider and use the information in the referenced standard consistent with current regulatory practices.

Electronic Access

You may also provide comments via the NRC's interactive rulemaking website through the NRC home page (http://www.nrc.gov). This site provides the availability to upload comments as files (any format), if your web browser supports that function. For information about the interactive rulemaking website, contact Ms. Carol Gallagher, (301) 415–5905 (e-mail: CAG@nrc.gov).

Finding of No Environmental Impact: Availability of Environmental Assessment

The Commission has determined under the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in subpart A of 10 CFR part 51, that this rule would not be a major Federal action significantly affecting the quality of the human environment and, therefore, an environment impact statement is not required. The Commission has prepared an Environmental Assessment supporting this finding of no significant environmental impact.

The NRC has sent a copy of the environmental assessment and a copy of the **Federal Register** Notice to every State liaison officer and requested their comments on the environmental assessment. The environmental assessment is available for inspection at the NRC Public Document Room, 2120 L Street NW., Washington, DC. Also, the NRC has committed itself to complying in all its actions with the Presidential Executive Order #12898—Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations, dated February 11, 1994. Therefore, the NRC also has determined that there are no disproportionate, high, and adverse impacts on minority and low-income populations. The NRC uses the following working definition of environmental justice: environmental justice means the fair treatment and meaningful involvement of all people, regardless of race, ethnicity, culture, income, or educational level with respect to the development, implementation, and enforcement of environmental laws, regulations and policies.

Paperwork Reduction Act Statement

This final rule does not contain a new or amended information collection requirement subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501, *et seq.*). Existing requirements were approved by the Office of Management and Budget, approval No. 3150–0011.

Public Protection Notification

If a document used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, an information collection.

Regulatory Analysis

The Commission has prepared a regulatory analysis which shows that the proposed amendment does not impose any new requirements or costs on current licensees who do not make changes to safety systems. However, licensees planning or proposing changes to power and instrumentation & control systems will be impacted because they will be required to meet the requirements of IEEE Std. 603–1991 for the changes even though the remainder of the plant power and I&C systems are only required to meet their current licensing basis. The draft regulatory analysis is available for inspection in the NRC Public Document Room, 2120 L Street, NW., Washington, DC.

Regulatory Flexibility Certification

As required by the Regulatory Flexibility Act of 1980 (5 U.S.C. 605(b)), the Commission certifies that this rule will not have a significant economic impact on small entities. This rule affects only the operation of nuclear power plants. The companies that own these plants do not fall within the scope of the definition of ''small entities'' set forth in the Regulatory Flexibility Act or the small business size standards adopted by the NRC (10 CFR 2.810). Since these companies are dominant in their service areas, this rule does not fall within the purview of the Act.

Backfit Analysis

The rule requires applicants and holders of new construction permits, new operating licenses, new final design approvals, new design certifications and combined licenses to comply with IEEE Std. 603–1991 (including the correction sheet dated January 30, 1995). Changes to protection systems in existing operating plants initiated on or after January 1, 1998 must meet the requirements of IEEE Std. 603–1991. IEEE Std. 279 will continue to apply to existing nuclear power plants that do not make any changes to their protection systems, but the rule permits the licensee the option of meeting IEEE Std. 603–1991.

The backfit rule was not intended to apply to regulatory actions which change expectations of prospective applicants, and therefore the backfit rule does not apply to the portion of the rule applicable to new construction permits, new operating licenses, new final design approvals, new design certifications and combined licenses. This rule does not change the licensing basis (i.e., IEEE Std. 279) for plants that do not intend to make any changes to their power and instrumentation and control systems. However, the rule would require future changes to existing power and instrumentation and control portions of protection systems to comply with the new standard. This would not be considered a backfit, since the changes are voluntarily initiated by the licensee, or separately imposed by the NRC after a separate backfit analysis. This is consistent with past NRC practice and the discussions on backfitting in ''Value-Impact Statement'' prepared for Revision 1 to Regulatory Guide 1.153. A copy of the Value-Impact Statement is available for inspection or copying for a fee in the Commission's Public Document Room at 2120 L Street NW., Washington, DC, under Task DG–1042.

In summary, the NRC has determined that the backfit rule, 10 CFR 50.109, does not apply to this direct final rule because it does not impose any backfits as defined in 10 CFR 50.109(a)(1) and, therefore, a backfit analysis has not been prepared for this direct final rule.

Small Business Regulatory Enforcement Fairness Act

In accordance with the Small Business Regulatory Enforcement Fairness Act of 1996, the NRC has determined that this action is not a major rule and has verified this determination with the Office of Information and Regulatory Affairs of OMB.

List of Subjects in 10 CFR Part 50

Antitrust, Classified information, Criminal penalties, Fire protection, Incorporation by reference, Intergovernmental relations, Nuclear power plants and reactors, Radiation protection, Reactor siting criteria, and Reporting and recordkeeping requirements.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended, the Energy Reorganizations Act of 1974, as amended, and 5 U.S.C. 552 and 553, the NRC is adopting the following amendment to 10 CFR part 50.

PART 50—DOMESTIC LICENSING OF PRODUCTION AND UTILIZATION FACILITIES

1. The authority citation for part 50 continues to read as follows:

Authority: Secs. 102, 103, 104, 105, 161, 182, 183, 186, 189, 68 Stat. 936, 937, 938, 948, 953, 954, 955, 956, as amended, sec. 234, 83 Stat. 1244, as amended (42 U.S.C. 2132, 2133, 2134, 2135, 2201, 2232, 2233, 2236, 2239, 2282); secs. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846).

Section 50.7 also issued under Pub. L. 95–601, sec, 10, 92 Stat. 2951 (42 U.S.C. 5851). Section 50.10 also issued under secs. 101, 185, 68 Stat. 955 as amended (42 U.S.C. 2131, 2235), sec. 102, Pub. L. 91–190, 83 Stat. 853 (42 U.S.C. 4332). Sections 50.13, and 50.54 (dd), and 50.103 also issued under sec. 108, 68 Stat. 939, as amended (42 U.S.C. 2138), Sections 50.23, 50.35, 50.55, and 50.56 also issued under sec. 185, 68 Stat. 955 (42 U.S.C. 2235), Sections 50.33a, 50.55a and Appendix Q also issued under sec. 102, Pub. L. 91–190, 83 Stat. 853 (42 U.S.C. 4332). Sections 50.34 and 50.54 also issued under sec. 204, 88 Stat. 1245 (42 U.S.C. 5844). Sections 50.58, 50.91, and 50.92 also issued under Pub. L. 97–415, 96 Stat. 2073 (42 U.S.C. 2239). Section 50.78 also issued under sec. 122, 68 Stat. 939 (42 U.S.C. 2152). Sections 50.80–50.81 also issued under sec. 184, 68 Stat. 954, as amended (42 U.S.C. 2234). Appendix F also issued under sec. 187, 68 Stat. 955 (42 U.S.C. 2237).

12. In § 50.55a, paragraph (h) is revised to read as follows:

§ 50.55a Codes and standards.

* * * * *

(h) *Protection and Safety Systems.* (1) IEEE Std. 603–1991 and the correction sheet dated January 30, 1995, which are referenced in paragraph (h)(3) and (h)(4), are approved for incorporation by reference by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A notice of any changes made to the material incorporated by reference will be published in the **Federal Register**. Copies of IEEE Std. 603–1991 may be purchased from the Institute of Electrical and Electronics Engineers Service Center, 445 Hoes Lane, Piscataway, NJ 08855. It is also available for inspection at the NRC Library, 11545 Rockville Pike, Rockville, MD 20852–2738, and at the Office of the Federal Register, 800 North Capital Street, NW, Suite 700, Washington, DC. IEEE Std. 279, which is referenced in paragraph (h)(2) of this section was approved for incorporation by reference by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of this standard are also available as indicated for IEEE Std. 603–1991.

(2) Definitions.

(I) For purposes of this paragraph the terms ''protection systems,'' ''safety systems,'' and ''safety-related systems'' are synonymous.

(ii) Changes to protection systems include modification, augmentation or replacement of protection systems permitted by license amendments, changes to protection systems made by licensees pursuant to 10 CFR 50.59, and plant specific departures from a design certification rule under 10 CFR part 52.

(3) Protection systems. For nuclear power plants with construction permits issued after January 1, 1971, but prior to January 1, 1998, protection systems must meet the requirements set forth either in the Institute of Electrical and Electronics Engineers (IEEE) Std. 279, ''Criteria for Protection Systems for Nuclear Power Generating Stations,'' or in IEEE Std. 603–1991, ''Criteria for Safety Systems for Nuclear Power Generating Stations,'' and the correction sheet dated January 30, 1995. However, changes to protection systems initiated on or after January 1, 1998 must meet the requirements set forth in IEEE Std. 603–1991, and the correction sheet dated January 30, 1995.

(4) Safety systems. For construction permits, operating licenses, final design approvals, design certifications and combined licenses issued on or after January 1, 1998, safety systems must meet the requirements set forth in IEEE Std. 603–1991, and the correction sheet, dated January 30, 1995.

Dated at Rockville, this 9th day of October, 1997.

For the Nuclear Regulatory Commission.

John C. Hoyle,

Secretary of the Commission.

[FR Doc. 97–27421 Filed 10–16–97; 8:45 am]

BILLING CODE 7590–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 97–ANE–38–AD; Amendment 39–10160; AD 97–21–07]

RIN 2120–AA64

Airworthiness Directives; AlliedSignal Inc. (Formerly Textron Lycoming) Model T5313B, T5317A, and T53 (Military) Turboshaft Engines

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule; request for comments.

SUMMARY: This amendment adopts a new airworthiness directive (AD) that is applicable to AlliedSignal Inc. (formerly Textron Lycoming) Model T5313B, T5317A, and T53 series military turboshaft engines approved for installation on aircraft certified in accordance with Section 21.25 of the Federal Aviation Regulations (FAR). This action requires a one-time visual inspection of accessory drive carrier assemblies for affected serial numbers (S/Ns) designating a defective assembly, and if the S/N is applicable, replacement with a serviceable assembly. This amendment is prompted by a report of an N2 overspeed condition due to a defective accessory drive carrier assembly. The actions specified in this AD are intended to prevent accessory drive carrier assembly failure, which could result in an N2 overspeed and an uncontained engine failure.

DATES: Effective November 3, 1997.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of November 3, 1997.

Comments for inclusion in the Rules Docket must be received on or before December 16, 1997.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), New England Region, Office of the Assistant Chief Counsel, Attention: Rules Docket No. 97–ANE–38–AD, 12 New England Executive Park, Burlington, MA 01803–5299. Comments may also be sent via the Internet using the following address: ''9-ad-engineprop@faa.dot.gov''. Comments sent via the Internet must contain the docket number in the subject line.

The service information referenced in this AD may be obtained from AlliedSignal Aerospace, Attn: Data Distribution, M/S 64–3/2101–201, P.O. Box 29003, Phoenix, AZ 85038–9003; telephone (602) 365–2493, fax (602) 365–5577. This information may be examined at the FAA, New England Region, Office of the Assistant Chief Counsel, 12 New England Executive Park, Burlington, MA; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Ray Vakili, Aerospace Engineer, Los Angeles Aircraft Certification Office, FAA, Transport Airplane Directorate, 3960 Paramount Blvd., Lakewood, CA 90712–4137; telephone (562) 627–5262, fax (562) 627–5210.

SUPPLEMENTARY INFORMATION: The Federal Aviation Administration has received a report of an N2 overspeed condition on an AlliedSignal Inc. (formerly Textron Lycoming) Model T5317A–1 turboshaft engine. The investigation revealed that the N2 overspeed condition was caused when the N2 overspeed governor bevel gear, which is part of the accessory drive carrier and cap assembly, shifted out of position. This gear shifting out of position was determined to be due to improper manufacturing of the accessory drive carrier and cap assembly, Part Number (P/N) 1–070–210–01, which is installed on the higher level assembly, accessory drive carrier assembly, P/N 1–070–220–03, 1–070–220–12, or 1–070–220–13. All accessory drive carrier assemblies, P/Ns 1–070–220–03, 1–070–220–12, and 1-070–220–13, installed after November 1, 1985, and have been identified by serial number (S/N) are subject to this inspection. This condition, if not corrected, could result in accessory drive carrier assembly failure, which could result in an N2 overspeed and an uncontained engine failure.

The FAA has reviewed and approved the technical contents of AlliedSignal Inc. Alert Service Bulletin (ASB) No. T5313B/17A–A0092, Revision 1, dated July 1, 1997; ASB No. T53–L–13B–A0092, dated June 4, 1997; and ASB No. T53–L–703–A0092, dated June 4, 1997. These ASBs describe procedures for performing a one-time visual inspection of accessory drive carrier assemblies for affected S/Ns designating a defective assembly, and if the S/N is applicable, replacement with a serviceable assembly.

Since an unsafe condition has been identified that is likely to exist or develop on other engines of the same type design, this AD is being issued to prevent accessory drive carrier assembly failure. This AD requires a one-time visual inspection of accessory drive carrier assemblies for affected S/Ns designating a potentially defective assembly, and if the S/N is applicable, replacement with a serviceable assembly. The actions are required to be accomplished in accordance with the ASBs described previously.

Since a situation exists that requires the immediate adoption of this regulation, it is found that notice and opportunity for prior public comment hereon are impracticable, and that good cause exists for making this amendment effective in less than 30 days.

Comments Invited

Although this action is in the form of a final rule that involves requirements affecting flight safety and, thus, was not preceded by notice and an opportunity

for public comment, comments are invited on this rule. Interested persons are invited to comment on this rule by submitting such written data, views, or arguments as they may desire. Communications should identify the rules docket number and be submitted in triplicate to the address specified under the caption **ADDRESSES.** All communications received on or before the closing date for comments will be considered, and this rule may be amended in light of the comments received. Factual information that supports the commenter's ideas and suggestions is extremely helpful in evaluating the effectiveness of the AD action and determining whether additional rulemaking action would be needed.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the rule that might suggest a need to modify the rule. All comments submitted will be available, both before and after the closing date for comments, in the rules docket for examination by interested persons. A report that summarizes each FAA-public contact concerned with the substance of this AD will be filed in the rules docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket Number 97–ANE–38–AD.'' The postcard will be date stamped and returned to the commenter.

The regulations adopted herein will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

The FAA has determined that this regulation is an emergency regulation that must be issued immediately to correct an unsafe condition in aircraft, and is not a ''significant regulatory action'' under Executive Order 12866. It has been determined further that this action involves an emergency regulation under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979). If it is determined that this emergency regulation otherwise would be significant under DOT Regulatory Policies and Procedures, a final regulatory evaluation will be prepared and placed in the rules docket. A copy of it, if filed, may be obtained from the rules docket at the location provided under the caption **ADDRESSES**.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

97–21–07 AlliedSignal Inc.: Amendment 39–10160. Docket 97–ANE–38–AD.

Applicability: AlliedSignal Inc. (formerly Textron Lycoming) Model T5313B, T5317A, and T53 series military turboshaft engines approved for installation on aircraft certified in accordance with Section 21.25 of the Federal Aviation Regulations (FAR), with accessory drive carrier assemblies, Part Numbers (P/Ns) 1–070–220–03, 1–070–220–12, and 1–070–220–13, that were installed after November 1, 1985, and have serial numbers (S/Ns) listed in AlliedSignal Inc. Alert Service Bulletins (ASBs) No. T5313B/17A–A0092, Revision 1, dated July 1, 1997; ASB No. T53–L–13B–A0092, dated June 4, 1997; or ASB No. T53–L–703–A0092, dated June 4, 1997. These engines are installed on but not limited to Bell Helicopter Textron Model 205A–1 and 205B series helicopters, Kaman Aircraft Corporation K–1200 series helicopters, and military helicopters certified in accordance with Section 21.25 of the FAR.

Note 1: A shipping records, engine logbooks, work orders, and parts invoices check may allow an owner or operator to determine if this AD applies.

Note 2: This airworthiness directive (AD) applies to each engine identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For engines that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (b) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

To prevent accessory drive carrier assembly failure, which could result in an N2 overspeed and an uncontained engine failure, accomplish the following:

(a) Within 100 hours time in service (TIS), or 6 months after the effective date of this AD, whichever occurs first, accomplish the following in accordance with AlliedSignal Inc. ASB No. T5313B/17A–A0092, Revision 1, dated July 1, 1997; ASB No. T53–L–13B–A0092, dated June 4, 1997; and ASB No. T53–L–703-A0092, dated June 4, 1997, as applicable:

(1) Visually inspect to determine if the accessory drive carrier assembly is marked with an affected S/N listed in the applicable ASBs.

(2) If the accessory drive carrier assembly is not marked with an affected S/N listed in the applicable ASB, no further action is required.

(3) If the accessory drive carrier assembly is marked with an affected S/N listed in the applicable ASB, or the serial number cannot be positively determined, remove the accessory drive carrier assembly from service and replace with a serviceable assembly.

(b) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Los Angeles Aircraft Certification Office. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Los Angeles Aircraft Certification Office.

Note 3: Information concerning the existence of approved alternative methods of compliance with this airworthiness directive, if any, may be obtained from the Los Angeles Aircraft Certification Office.

(c) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the aircraft to a location where the requirements of this AD can be accomplished.

(d) The actions required by this AD shall be done in accordance with the following AlliedSignal Inc. ASBs:

Document No.	Pages	Revision	Date
T5313B/17A–A0092 ..... Total pages: 7	1–7	1	July 1, 1997.
T53–L–13B–A0092 ..... Total pages: 7	1–7	Original	June 4, 1997.

Document No.	Pages	Revision	Date
T53–L–703–A0092 ..... Total pages: 7	1–7	Original	June 4, 1997.

This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from AlliedSignal Aerospace, Attn: Data Distribution, M/S 64–3/2101–201, P.O. Box 29003, Phoenix, AZ 85038–9003; telephone (602) 365–2493, fax (602) 365–5577. Copies may be inspected at the FAA, New England Region, Office of the Assistant Chief Counsel, 12 New England Executive Park, Burlington, MA; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(e) This amendment becomes effective on November 3, 1997.

Issued in Burlington, Massachusetts, on October 8, 1997.

Jay J. Pardee,

Manager, Engine and Propeller Directorate, Aircraft Certification Service.

[FR Doc. 97–27350 Filed 10–16–97; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 97–NM–220–AD; Amendment 39–10164; AD 97–21–11]

RIN 2120–AA64

Airworthiness Directives; Short Brothers Model SD3–30 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule; request for comments.

SUMMARY: This amendment adopts a new airworthiness directive (AD) that is applicable to all Short Brothers Model SD3–30 series airplanes. This action requires a one-time inspection to measure the depth of the skin flutes of the skin panels of the rudder and elevators, and repair, if necessary. This amendment is prompted by reports indicating that, due to a manufacturing process error, the depth of certain skin flutes of the rudder and elevators is less than the design specification. The actions specified in this AD are intended to prevent structural damage and/or loss of the rudder or elevators if the airplane is operated under ultimate load conditions, which could result in reduced controllability of the airplane.

DATES: Effective November 3, 1997.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of November 3, 1997.

Comments for inclusion in the Rules Docket must be received on or before November 17, 1997.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–103, Attention: Rules Docket No. 97–NM–220–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056.

The service information referenced in this AD may be obtained from Short Brothers, Airworthiness & Engineering Quality, P.O. Box 241, Airport Road, Belfast BT3 9DZ, Northern Ireland. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Gary D. Lium, Aerospace Engineer, Standardization Branch, ANM–113, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 227–1112; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION: The Civil Aviation Authority (CAA), which is the airworthiness authority for the United Kingdom, recently notified the FAA that an unsafe condition may exist on all Short Brothers Model SD3–30 series airplanes. The CAA advises of findings that the depth of the skin flutes of the port and starboard skin panels of the rudder and elevators is less than the appropriate depth specified by the design specification. The problem was noticed during the production of skin flutes for the SD3–60 SHERPA series airplanes, and it was noted that the same manufacturing process was used for Model SD3–30 series airplanes. (The manufacturer advises that all SD3–60 SHERPA series airplanes have been inspected, and that no unsafe condition exists with regard to the skin flutes on these airplanes; therefore, Model SD3–60 SHERPA series airplanes are not included in the applicability of this AD.) Such inadequate depth of the skin flutes, if not corrected, could result in structural damage and/or loss of the rudder or elevators if the airplane is operated under ultimate load conditions, and consequent reduced controllability of the airplane.

Explanation of Relevant Service Information

The manufacturer has issued Service Bulletin SD330–55–19, dated February 11, 1997, which describes procedures for performing a one-time inspection to measure the depth of the skin flutes of the skin panels of the rudder and elevators, and repair, if necessary. The CAA classified this service bulletin as mandatory and issued British airworthiness directive 006–02–97 in order to assure the continued airworthiness of these airplanes in the United Kingdom.

FAA's Conclusions

This airplane model is manufactured in the United Kingdom and is type certificated for operation in the United States under the provisions of section 21.29 of the Federal Aviation Regulations (14 CFR 21.29) and the applicable bilateral airworthiness agreement. Pursuant to this bilateral airworthiness agreement, the CAA has kept the FAA informed of the situation described above. The FAA has examined the findings of the CAA, reviewed all available information, and determined that AD action is necessary for products of this type design that are certificated for operation in the United States.

Explanation of Requirements of Rule

Since an unsafe condition has been identified that is likely to exist or develop on other airplanes of the same type design registered in the United States, this AD is being issued to prevent structural damage and/or loss of the rudder or elevators if the airplane is operated under ultimate load conditions, and consequent reduced controllability of the airplane. This AD requires a one-time inspection to measure the depth of the skin flutes of the skin panels of the rudder and elevators, and repair, if necessary. The inspection is required to be accomplished in accordance with the service bulletin described previously. The repair of any discrepant skin flute is required to be accomplished in accordance with a method approved by the FAA.

Determination of Rule's Effective Date

Since a situation exists that requires the immediate adoption of this regulation, it is found that notice and opportunity for prior public comment hereon are impracticable, and that good cause exists for making this amendment effective in less than 30 days.

Comments Invited

Although this action is in the form of a final rule that involves requirements affecting flight safety and, thus, was not preceded by notice and an opportunity for public comment, comments are invited on this rule. Interested persons are invited to comment on this rule by submitting such written data, views, or arguments as they may desire. Communications shall identify the Rules Docket number and be submitted in triplicate to the address specified under the caption **ADDRESSES.** All communications received on or before the closing date for comments will be considered, and this rule may be amended in light of the comments received. Factual information that supports the commenter's ideas and suggestions is extremely helpful in evaluating the effectiveness of the AD action and determining whether additional rulemaking action would be needed.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the rule that might suggest a need to modify the rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report that summarizes each FAA-public contact concerned with the substance of this AD will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this rule must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket Number 97–NM–220–AD.'' The postcard will be date stamped and returned to the commenter.

Regulatory Impact

The regulations adopted herein will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

The FAA has determined that this regulation is an emergency regulation that must be issued immediately to correct an unsafe condition in aircraft, and that it is not a ''significant regulatory action'' under Executive Order 12866. It has been determined further that this action involves an emergency regulation under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979). If it is determined that this emergency regulation otherwise would be significant under DOT Regulatory Policies and Procedures, a final regulatory evaluation will be prepared and placed in the Rules Docket. A copy of it, if filed, may be obtained from the Rules Docket at the location provided under the caption **ADDRESSES.**

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

97–21–11 Short Brothers, PLC: Amendment 39–10164. Docket 97–NM–220–AD.

Applicability: All Model SD3–30 series airplanes, certificated in any category.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been otherwise modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been otherwise modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (b) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

To prevent structural damage and/or loss of the rudder or elevators if the airplane is operated under ultimate load conditions, and consequent reduced controllability of the airplane, accomplish the following:

(a) Within 90 days of the effective date of this AD, accomplish a one-time inspection to measure the depth of the skin flutes of the port and starboard skin panels of the rudder and elevators, in accordance with Short Brothers Service Bulletin SD330–55–19, dated February 11, 1997.

(1) If the depth of the skin flutes is within the limits specified in the service bulletin, no further action is required by this AD.

(2) If the depth of the skin flutes is beyond the limits specified in the service bulletin, prior to further flight, repair it in accordance with a method approved by the Manager, Standardization Branch, ANM–113, FAA, Transport Airplane Directorate.

(b) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Standardization Branch, ANM–113. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Standardization Branch, ANM–113.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Standardization Branch, ANM–113.

(c) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

(d) The inspection shall be done in accordance with Short Brothers Service Bulletin SD330–55–19, dated February 11, 1997. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Short Brothers, Airworthiness & Engineering Quality, P.O. Box 241, Airport Road, Belfast BT3 9DZ, Northern Ireland. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(e) This amendment becomes effective on November 3, 1997.

Issued in Renton, Washington, on October 9, 1997.

James V. Devany,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 97–27355 Filed 10–16–97; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 97–NM–265–AD; Amendment 39–10163; AD 97–21–10]

RIN 2120–AA64

Airworthiness Directives; Airbus Model A319, A320, and A321 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule; request for comments.

SUMMARY: This amendment adopts a new airworthiness directive (AD) that is applicable to certain Airbus Model A319, A320, and A321 series airplanes. This action requires revising the FAA-approved Airplane Flight Manual to increase monitoring of the flight path of the airplane to detect certain software anomalies of the flight management guidance system (FMGS), and take appropriate corrective actions. This amendment is prompted by the issuance of mandatory continuing airworthiness information by a foreign civil airworthiness authority. The actions specified in this AD are intended to ensure that the flightcrew detects and corrects an unintended flight path if certain software anomalies of the FMGS occur, which could result in an increased risk of collision with terrain or other airplanes.

DATES: Effective November 3, 1997.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of November 3, 1997.

Comments for inclusion in the Rules Docket must be received on or before November 17, 1997.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–103, Attention: Rules Docket No. 97–NM–265–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056.

The service information referenced in this AD may be obtained from Airbus Industrie, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Charles Huber, Aerospace Engineer, Standardization Branch, ANM–113, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 227–2589; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION: The Direction Générale de l'Aviation Civile (DGAC), which is the airworthiness authority for France, recently notified the FAA that an unsafe condition may exist on certain Airbus Model A319, A320, and A321 series airplanes. The DGAC advises that a software anomaly of the flight management guidance system (FMGS) may affect transition computations. This condition, if not detected and corrected, could result in an unintended flight path, and consequently, result in an increased risk of collision with terrain or other airplanes.

Explanation of Relevant Service Information

Airbus has issued Model A319/320/321 Flight Manual Temporary Revision 4.03.00/02, dated May 28, 1997, which describes procedures for monitoring the flight path of the airplane to detect certain software anomalies of the FMGS, and corrective actions. Accomplishment of the actions specified in the temporary revision is intended to adequately address the identified unsafe condition. The DGAC classified this temporary revision as mandatory and issued French airworthiness directive 97–153–100(B), dated July 16, 1997, in order to assure the continued airworthiness of these airplanes in France.

FAA's Conclusions

These airplane models are manufactured in France and are type certificated for operation in the United States under the provisions of section 21.29 of the Federal Aviation Regulations (14 CFR 21.29) and the applicable bilateral airworthiness agreement. Pursuant to this bilateral airworthiness agreement, the DGAC has kept the FAA informed of the situation described above. The FAA has examined the findings of the DGAC, reviewed all available information, and determined that AD action is necessary for products of this type design that are certificated for operation in the United States.

Explanation of Requirements of Rule

Since an unsafe condition has been identified that is likely to exist or develop on other airplanes of the same type design registered in the United States, this AD is being issued to ensure the flightcrew detects and corrects an unintended flight path if certain software anomalies of the FMGS occur, which could result in an increased risk of collision with terrain or other airplanes. This AD requires revising the Normal Procedures Section of the FAA-approved Airplane Flight Manual (AFM) to increase monitoring of the flight path of the airplane to detect certain software anomalies of the FMGS, and corrective actions. The actions are required to be accomplished in accordance with the temporary revision described previously.

Interim Action

This is considered to be interim action until final action is identified, at which time the FAA may consider further rulemaking.

Determination of Rule's Effective Date

Since a situation exists that requires the immediate adoption of this regulation, it is found that notice and opportunity for prior public comment hereon are impracticable, and that good cause exists for making this amendment effective in less than 30 days.

Comments Invited

Although this action is in the form of a final rule that involves requirements affecting flight safety and, thus, was not preceded by notice and an opportunity for public comment, comments are invited on this rule. Interested persons are invited to comment on this rule by submitting such written data, views, or arguments as they may desire. Communications shall identify the Rules Docket number and be submitted in triplicate to the address specified under the caption **ADDRESSES.** All communications received on or before the closing date for comments will be considered, and this rule may be amended in light of the comments received. Factual information that supports the commenter's ideas and suggestions is extremely helpful in evaluating the effectiveness of the AD action and determining whether additional rulemaking action would be needed.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the rule that might suggest a need to modify the rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report that summarizes each FAA-public contact concerned with the substance of this AD will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this rule must submit a self-addressed, stamped postcard on which the following

statement is made: ''Comments to Docket Number 97–NM–265–AD.'' The postcard will be date stamped and returned to the commenter.

Regulatory Impact

The regulations adopted herein will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

The FAA has determined that this regulation is an emergency regulation that must be issued immediately to correct an unsafe condition in aircraft, and that it is not a ''significant regulatory action'' under Executive Order 12866. It has been determined further that this action involves an emergency regulation under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979). If it is determined that this emergency regulation otherwise would be significant under DOT Regulatory Policies and Procedures, a final regulatory evaluation will be prepared and placed in the Rules Docket. A copy of it, if filed, may be obtained from the Rules Docket at the location provided under the caption **ADDRESSES.**

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

97–21–10 Airbus Industrie: Amendment 39–10163. Docket 97–NM–265–AD.

Applicability: Model A319, A320, and A321 series airplanes, certificated in any category; on which any of the following Airbus Modifications have been installed:

Affected model(s)	Airbus modification installed
A319 and A321.	25469 (reference Airbus Service Bulletin A320–22–1054).
A319, A320, and A321.	26093.
A320	24065 (reference Airbus Service Bulletin A320–22–1040) or 24067 (reference Airbus Service Bulletin A320–22–1039).
A320	25314 (reference Airbus Service Bulletin A320–22–1051) or 25315 (reference Airbus Service Bulletin A320–22–1050).
A320 and A321.	24064 (reference Airbus Service Bulletin A320–22–1034) or 24066 (reference Airbus Service Bulletin A320–22–1029).
A320 and A321.	25199 (reference Airbus Service Bulletin A320–22–1045) or 25200 (reference Airbus Service Bulletin A320–22–1046).
A320 and A321.	25240 (reference Airbus Service Bulletin A320–22–1033) or 25274 (reference Airbus Service Bulletin A320–22–1056).
A319, A320, and A321.	26243.
A319 and A320.	26717.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (b) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

To ensure that the flightcrew detects and corrects an unintended flight path if certain software anomalies of the FMGS occur, which could result in an increased risk of collision with terrain or other airplanes, accomplish the following:

(a) Within 10 days after the effective date of this AD, revise the Normal Procedures Section of the FAA-approved Airplane Flight Manual (AFM) by inserting a copy of Model A319/320/321 Flight Manual Temporary Revision 4.03.00/02, dated May 28, 1997, into the AFM.

Note 2: When the temporary revision specified in paragraph (a) of this AD has been incorporated into the general revisions of the AFM, the general revisions may be inserted in the AFM, provided the information contained in the general revisions is identical to that specified in Model A319/320/321 Flight Manual Temporary Revision 4.03.00/02.

(b) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Standardization Branch, ANM–113, FAA, Transport Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Operations Inspector, who may add comments and then send it to the Manager, Standardization Branch, ANM–113.

Note 3: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Standardization Branch, ANM–113.

(c) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

(d) The AFM revision shall be done in accordance with Model A319/320/321 Flight Manual Temporary Revision 4.03.00/02, dated May 28, 1997. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Airbus Industrie, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

Note 4: The subject of this AD is addressed in French airworthiness directive 97–153–100(B), dated July 16, 1997.

(e) This amendment becomes effective on November 3, 1997.

Issued in Renton, Washington, on October 9, 1997.

James V. Devany,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 97–27353 Filed 10–16–97; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 97–AGL–22]

Establishment of Class E Airspace; Sauk Centre, MN

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action establishes Class E airspace at Sauk Centre, MN. A Global Positioning System (GPS) Standard Instrument Approach Procedure (SIAP) to Runway (RWY) 32 has been

developed for Sauk Centre Municipal Airport. Controlled airspace extending upward from 700 to 1200 feet above ground level (AGL) is needed to contain aircraft executing the approach. The intended effect of this action is to provide segregation of aircraft using instrument approach procedures in instrument conditions from other aircraft operating in visual weather conditions.

EFFECTIVE DATE: 0901 UTC, January 1, 1998.

FOR FURTHER INFORMATION CONTACT: Michelle M. Behm, Air Traffic Division, Airspace Branch, AGL–520, Federal Aviation Administration, 2300 East Devon Avenue, Des Plaines, Illinois 60018, telephone (847) 294–7568.

SUPPLEMENTARY INFORMATION:

History

On Friday, July 25, 1997, the FAA proposed to amend part 71 of the Federal Aviation Regulations (14 CFR part 71) to establish Class E airspace at Sauk Centre, MN (62 FR 39979). The proposal was to add controlled airspace extending upward from 700 to 1200 feet AGL to contain Instrument Flight Rules (IFR) operations in controlled airspace during portions of the terminal operation and while transmitting between the enroute and terminal environments.

Interested parties were invited to participate in this rulemaking proceeding by submitting written comments on the proposal to the FAA. No comments objecting to the proposal were received. Class E airspace designations for airspace areas extending upward from 700 feet or more above the surface of the earth are published in paragraph 6005 of FAA Order 7400.9E, dated September 10, 1997, and effective September 16, 1997, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document will be published subsequently in the Order.

The Rule

This amendment to part 71 of the Federal Aviation Regulations (14 CFR part 71) establishes Class E airspace at Sauk Centre, MN, to accommodate aircraft executing the GPS RWY 32 SIAP at Sauk Centre Municipal Airport. Controlled airspace extending upward from 700 to 1200 feet AGL is needed to contain aircraft executing the approach. The area will be depicted on appropriate aeronautical charts.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this regulation—(1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—[AMENDED]

1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9E, Airspace Designations and Reporting Points, dated September 10, 1997, and effective September 16, 1997, is amended as follows:

Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.

* * * * *

AGL MN E5 Sauk Centre, MN [New]

Sauk Centre Municipal Airport, MN
(Lat. 45°42′24″ N, long. 94°56′00″ W)

That airspace extending upward from 700 feet above the surface within a 6.4-mile radius of the Sauk Centre Municipal Airport.

* * * * *

Issued in Des Plaines, Illinois on September 15, 1997.

Maureen Woods,

Manager, Air Traffic Division.

[FR Doc. 97–27387 Filed 10–16–97; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 97–AEA–25]

Amendment to Class E Airspace; Kutztown, PA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action revises the Class E airspace extending upward from 700 feet Above Ground Level (AGL) at Kutztown, PA. The development of a Global Positioning System (GPS) Standard Instrument Approach Procedure (SIAP) to Runway (RWY) 17 at Kutztown Airport has made this action necessary. This action is intended to provide adequate Class E airspace to contain instrument flight rules (IFR) operations for aircraft executing the GPS SIAP to RWY 17 at Kutztown, PA.

EFFECTIVE DATE: 0901 UTC, January 1, 1998.

FOR FURTHER INFORMATION CONTACT: Mr. Francis Jordan, Airspace Specialist, Airspace Branch, AEA–520, Air Traffic Division, Eastern Region, Federal Aviation Administration, Federal Building #111, John F. Kennedy International Airport, Jamaica, New York 11430, telephone: (718) 553–4521.

SUPPLEMENTARY INFORMATION:

History

On June 24, 1997, a proposal to amend Part 71 of the Federal Aviation Regulations (14 CFR Part 71) to revise the Class E airspace at Kutztown, PA, was published in the **Federal Register** (62 FR 34026). A GPS SIAP to RWY 17 developed for Kutztown Airport, Kutztown, PA, requires the revision of the Class E airspace at the airport. The proposal would revise the controlled airspace extending upward from 700 feet AGL to contain IFR operations in controlled airspace during portions of the terminal operation and while transitioning between the enroute and terminal environments.

Interested parties were invited to participate in this rulemaking proceeding by submitting written comments on the proposal to the FAA. No comments to the proposal were received. The rule is adopted as proposed.

The coordinates for this airspace docket are based on North American Datum 83. Class E airspace areas designations for airspace extending

upward from 700 feet AGL are published in paragraph 6005 of FAA Order 7400.9E, dated September 10, 1997, and effective September 16, 1997, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document will be published subsequently in the Order.

The Rule

This amendment to Part 71 of the Federal Aviation Regulations (14 CFR Part 71) amends the Class E airspace located at Kutztown, PA, to provide controlled airspace extending upward from 700 feet AGL for aircraft executing a GPS SIAP to RWY 17.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this regulation—(1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation it is certified that this rule will not have significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—[AMENDED]

1. The authority citation for 14 CFR Part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; EO 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.9E, Airspace Designations and Reporting Points, dated September 10, 1997, and effective September 16, 1997, is amended as follows:

Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.

* * * * *

AEA PA AEA E5 Kutztown, PA [Revised]

Kutztown Airport, PA

(Lat. 40°30′13″ N., long. 75°47′14″ W.)

That airspace extending upward from 700 feet above the surface within a 6.5-mile radius of Kutztown Airport and within 3.5 miles northeast and 5.3 miles southwest of the 340° bearing from the airport extending from the 6.5-mile radius to 17 miles northwest of the airport, excluding the portions that coincide with the Allentown, PA, Reading, PA, and Lehighton, PA, Class E airspace areas.

* * * * *

Issued in Jamaica, New York, on August 20, 1997.

Franklin D. Hatfield,

Manager, Air Traffic Division, Eastern Region.

[FR Doc. 97–27374 Filed 10–16–97; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 97–AEA–19]

Establishment of Class E Airspace; Zelienople, PA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action establishes Class E airspace extending upward from 700 feet Above Ground Level (AGL) at Zelienople, PA. The development of Global Positioning System (GPS) Standard Instrument Approach Procedures (SIAP) to Runway (RWY) 17 and RWY 35 at Zelienople Airport has made this action necessary. This action is intended to provide adequate Class E airspace to contain Instrument Flight Rules (IFR) operations for aircraft executing the GPS RWY 17 and GPS RWY 35 SIAPs at Zelienople, PA.

EFFECTIVE DATE: 0901 UTC, January 1, 1998.

FOR FURTHER INFORMATION CONTACT: Mr. Francis Jordan, Airspace Specialist, Airspace Branch, AEA–520, Air Traffic Division, Eastern Region, Federal Aviation Administration, Federal Building #111, John F. Kennedy International Airport, Jamaica, New York 11430; telephone (718) 553–4521.

SUPPLEMENTARY INFORMATION:

History

On April 3, 1997, a proposal to amend Part 71 of the Federal Aviation Regulations (14 CFR Part 71) to establish Class E airspace at Zelienople, PA, was published in the **Federal Register** (62 FR 15864). A GPS RWY 17 SIAP and a GPS RWY 35 SIAP developed for Zelienople Airport, Zelienople, PA, requires the establishment of Class E airspace at the airport. The proposal would establish controlled airspace extending upward from 700 feet AGL to contain IFR operations in controlled airspace during portions of the terminal operation and while transitioning between the enroute and terminal environments.

Interested parties were invited to participate in this rulemaking proceeding by submitting written comments on the proposal to the FAA. No comments objecting to the proposal were received. The rule is adopted as proposed.

The coordinates for this airspace docket are based on North American Datum 83. Class E airspace areas designations for airspace extending upward from 700 feet or more above the surface of the earth are published in paragraph 6005 of FAA Order 7400.9E, dated September 10, 1997, and effective September 16, 1997, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document will be published subsequently in the Order.

The Rule

This amendment to Part 71 of the Federal Aviation Regulations (14 CFR Part 71) establishes Class E airspace located at Zelienople, PA, to provide controlled airspace extending upward from 700 feet AGL for aircraft executing the GPS RWY 17 SIAP and GPS RWY 35 SIAP to Zelienople Airport.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this regulation—(1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule will not have significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—[AMENDED]

1. The authority citation for Part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; EO 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.9E, Airspace Designations and Reporting Points, dated September 10, 1997, and effective September 16, 1997, is amended as follows:

Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.

* * * * *

AEA PA AEA E5 Zelienople, PA [New]

Zelienople Airport, PA
(Lat. 40°48′06″ N., long. 80°09′38″ W.)

That airspace extending upward from 700 feet above the surface within a 6-mile radius of Zelienople Airport, excluding the portions that coincide with the Butler, PA, and Beaver Falls, PA, Class E airspace areas.

* * * * *

Issued in Jamaica, New York, on September 5, 1997.

Franklin D. Hatfield,

Manager, Air Traffic Division, Eastern Region.

[FR Doc. 97–27365 Filed 10–16–97; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. 97–ACE–7]

Amendment to Class E Airspace; Belleville, KS

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Direct final rule; request for comments.

SUMMARY: This action amends the Class E airspace are at Belleville Municipal Airport, Belleville, KS. A review of the airspace for Belleville Municipal Airport indicates it does not meet the criteria for 700 feet Above Ground Level (AGL) Class E airspace as required in FAA Order 7400.2D. The distance required for an aircraft to reach 1200 feet Mean Sea Level (MSL) is based on a standard climb gradient of 200 feet per mile, plus the distance from the Airport Reference Point (ARP) to the end of the outermost runway. Any fractional part of a mile is converted to the next higher tenth of a mile increment. The area has been enlarged to conform to the criteria of FAA Order 7400.2D. The intended effect of this rule is to provide controlled Class E airspace for aircraft executing instrument approaches and to conform to the requirements of FAA Order 7400.2D.

DATES: *Effective date:* 0901 UTC, February 26, 1998. *Comment date:* Comments must be received on or before December 1, 1997.

ADDRESSES: Send comments regarding the rule in triplicate to: Manager, Airspace Branch, Air Traffic Division, ACE–520, Federal Aviation Administration, Docket Number 97–ACE–7, 601 East 12th St., Kansas City, MO 64106.

The official docket may be examined in the Office of the Assistant Chief Counsel for the Central Region at the same address between 9:00 a.m. and 3:00 p.m., Monday through Friday, except Federal holidays.

An informal docket may also be examined during normal business hours in the Air Traffic Division at the same address listed above.

FOR FURTHER INFORMATION CONTACT:

Kathy Randolph, Air Traffic Division, Airspace Branch, ACE–520C, Federal Aviation Administration, 601 East 12th Street, Kansas City, Missouri 64106: telephone: (816) 426–3408.

SUPPLEMENTARY INFORMATION: A review of the airspace for Belleville Municipal Airport indicates it does not meet the criteria for 700 feet AGL Class E airspace as required in FAA Order 7400.2D. The distance required for an aircraft to reach 1200 feet MSL is based on a standard climb gradient of 200 feet per mile plus the distance from the ARP to the end of the outermost runway. Any fractional part of a mile is converted to the next higher tenth of a mile. The amendment of Class E airspace at Belleville, KS, will provide additional controlled airspace to segregate aircraft operating under Instrument Flight Rules (IFR). The area will be depicted on appropriate aeronautical charts. Class E airspace areas extending from 700 feet or more above the surface of the earth are published in paragraph 6005 of FAA Order 7400.9E, dated September 10, 1997, and effective September 16, 1997, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document will be published subsequently in the Order.

The Direct Final Rule Procedure

The FAA anticipates that this regulation will not result in adverse or negative comment and, therefore, is issuing it as a direct final rule. Previous actions of this nature have not been controversial and have not resulted in adverse comments or objections. The amendment will enhance safety for all flight operations by designating an area where VFR pilots may anticipate the presence of IFR aircraft at lower altitudes, especially during inclement weather conditions. A greater degree of safety is achieved by depicting the area on aeronautical charts. Unless a written adverse or negative comment, or a written notice of intent to submit an adverse or negative comment is received within the comment period, the regulation will become effective on the date specified above. After the close of the comment period, the FAA will publish a document in the **Federal Register** indicating that no adverse or negative comments were received and confirming the date on which the final rule will become effective. If the FAA does receive, within the comment period, an adverse or negative comment, or written notice of intent to submit such a comment, a document withdrawing the direct final rule will be published in the **Federal Register**, and a notice of proposed rulemaking may be published with a new comment period.

Comments Invited

Although this action is in the form of a final rule and was not preceded by a notice of proposed rulemaking, comments are invited to this rule. Interested persons are invited to comment on this rule by submitting such written data, views, or arguments as they may desire. Communications should identify the Rules Docket number and be submitted in triplicate to the address specified under the caption **ADDRESSES**. All communications received on or before the closing date for comments will be considered, and this rule may be amended or withdrawn in light of the comments received. Factual information that supports the commenter's ideas and suggestions is extremely helpful in evaluating the effectiveness of this action and determining whether additional rulemaking action would be needed.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy-related aspects of the rule that might suggest a need to modify the rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by

interested persons. A report that summarizes each FAA-public contact concerned with the substance of this action will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this rule must submit a self-addressed, stamped postcard or which the following statement is made: ''Comments to Docket No. 97–ACE–7.'' The postcard will be dated stamped and returned to the commenter.

Agency Findings

The regulations adopted herein will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

The FAA has determined that this regulation is noncontroversial and unlikely to result in adverse or negative comments. For the reasons discussed in the preamble, I certify that this regulation (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under Department of Transportation (DOT) Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

Accordingly, the Federal Aviation Administration amends part 71 of the Federal Aviation Regulations (14 CFR part 71) as follows:

PART 71—DESIGNATION OF CLASS A, CLASS B, CLASS C, CLASS D, AND CLASS E AIRSPACE AREAS; AIRWAYS; ROUTES; AND REPORTING POINTS

1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.9E, Airspace Designations and Reporting Points, dated September 10, 1997, and effective September 16, 1997, is amended as follows:

Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth

* * * * *

ACE KS E5 Belleville, KS [Revised]

Belleville Municipal Airport, KS.
(Lat. 39°49′04″ N., long. 97°39′35″ W.)
Republican NDB
(Lat. 39°548′48″ N. long. 97°39′30″ W.)

That airspace extending upward from 700 feet above the surface within a 6.4-mile radius of the Belleville Municipal Airport and within 2.6 miles each side of the 195° bearing from Republican NDB extending from the 6.4-mile radius to 7.4 miles south of the airport and within 2.6 miles each side of the 356° bearing from the Republican NDB extending from the 6.4-Mile radius to 7.4 miles north of the airport.

* * * * *

Issued in Kansas City, MO, on August 29, 1997.

Christopher R. Blum,

Acting Manager, Air Traffic Division, Central Region.

[FR Doc. 97–27363 Filed 10–16–97; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. 97–ACE–10]

Amendment to Class E Airspace, Kansas City, Richards-Gebaur Airport, MO

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Direct final rule; request for comments.

SUMMARY: This action amends the Class E airspace area at Richards-Gebaur Airport, Kansas City, MO. The FAA has developed a Nondirectional Radio Beacon (NDB) Runway (RWY) 1 Standard Instrument Approach Procedure (SIAP) to serve the Richards-Gebaur Airport. The intended effect of this action is to provide additional controlled airspace extending upward from 700 feet Above Ground Level (AGL) to accommodate this SIAP, and to provide segregation of aircraft using instrument approach procedures in instrument conditions from other aircraft operating in visual weather conditions at this airport. The enlarged area will contain the new NDB RWY 1 SIAP in controlled airspace. A minor correction has been made to the Airport Reference Point (ARP) geographic coordinates of the Richard-Gebaur Airport and is reflected in this document.

DATES: *Effective date:* 0901 UTC, February 26, 1998. *Comment date:* Comments must be received on or before November 15, 1997.

ADDRESSES: Send comments regarding the rule in triplicate to: Manager, Airspace Branch, Air Traffic Division, ACE–520, Federal Aviation Administration, Docket Number 97–ACE–10, 601 East 12th St. Kansas City, MO 64106.

The official docket may be examined in the Office of the Assistant Chief Counsel for the Central Region at the same address between 9:00 a.m. and 3:00 p.m., Monday through Friday, except Federal holidays.

An informal docket may also be examined during normal business hours in the Air Traffic Division at the same address listed above.

FOR FURTHER INFORMATION CONTACT: Kathy Randolph, Air Traffic Division, Airspace Branch, ACE–520C, Federal Aviation Administration, 601 East 12th Street, Kansas City, MO 64106; telephone: (816) 426–3408.

SUPPLEMENTARY INFORMATION: The FAA has developed a NDB RWY 1 SIAP at Richards-Gebaur Airport, Kansas City, MO. The amendment to Class E airspace at Richards-Gebaur Airport, MO, will provide additional controlled airspace at and above 700 feet AGL in order to contain the new SIAP within controlled airspace, and thereby facilitate separation of aircraft operating under instrument flight rules (IFR). The area will be depicted on appropriate aeronautical charts. Class E airspace areas extending from 700 feet or more above the surface of the earth are published in paragraph 6005 of FAA Order 7400.9E, dated September 10, 1997, and effective September 16, 1997, which is incorporated by reference in 14 CFR 71.1. A minor correction has been made to ARP geographic coordinates for the Richards-Gebaur Airport and is reflected in this docket. The ARP geographic coordinates and the Class E airspace designation listed in this document will be published subsequently in the Order.

The Direct Final Rule Procedure

The FAA anticipates that this regulation will not result in adverse or negative comment and, therefore, is issuing it as a direct final rule. Previous actions of this nature have not been controversial and have not resulted in adverse comments or objections. The

amendment will enhance safety for all flight operations by designating an area where VFR pilots may anticipate the presence of IFR aircraft at lower altitudes, especially during inclement weather conditions. A greater degree of safety is achieved by depicting the area on aeronautical charts. Unless a written adverse or negative comment, or a written notice of intent to submit an adverse or negative comment is received within the comment period, the regulation will become effective on the date specified above. After the close of the comment period, the FAA will publish a document in the **Federal Register** indicating that no adverse or negative comments were received and confirming the date on which the final rule will become effective. If the FAA does receive, within the comment period, an adverse or negative comment, or written notice of intent to submit such a comment, a document withdrawing the direct final rule will be published in the **Federal Register,** and a notice of proposed rulemaking may be published with a new comment period.

Comments Invited

Although this action is in the form of a final rule and was not preceded by a notice of proposed rulemaking, comments are invited on this rule. Interested persons are invited to comment on this rule by submitting such written data, views, or arguments as they may desire. Communications should identify the Rules Docket number and be submitted in triplicate to the address specified under the caption **ADDRESSES.** All communications received on or before the closing date for comments will be considered, and this rule may be amended or withdrawn in light of the comments received. Factual information that supports the commenter's ideas and suggestions is extremely helpful in evaluating the effectiveness of this action and determining whether additional rulemaking action would be needed.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy-related aspects of the rule that might suggest a need to modify the rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules docket for examination by interested persons. A report that summarizes each FAA-public contact concerned with the substance of this action will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this rule must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. 97–ACE–10.'' The postcard will be date stamped and returned to the commenter.

Agency Findings

The regulations adopted herein will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

The FAA has determined that this regulation is noncontroversial and unlikely to result in adverse or negative comments. For the reasons discussed in the preamble, I certify that this regulation (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under Department of Transportation (DOT) Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, navigation (air).

Adoption of the Amendment

Accordingly, the Federal Aviation Administration amends part 71 of the Federal Aviation Regulations (14 CFR Part 71) as follows:

PART 71—DESIGNATION OF CLASS A, CLASS B, CLASS C, CLASS D, AND CLASS E AIRSPACE AREAS; AIRWAYS; ROUTES; AND REPORTING POINTS

1. The authority citation for Part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration order 7400.9E, Airspace Designations and Reporting Points, dated September 10, 1997, and effective September 16, 1997, is amended as follows:

Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth

* * * * *

ACE MO E5 Kansas City, Richards-Gebaur Airport, MO [Revised]

Richards-Gebaur Airport, MO.
(Lat. 38°50′39″ N., long. 94°33′37″ W.)

That airspace extending upward from 700 feet above the surface within a 6.8-mile radius of Richards-Gebaur Airport and within 3 miles each side of the Richards-Gebaur ILS localizer course extending from the 6.8 mile radius to 7 miles north of the airport and within 3 miles each side of the Richards-Gebaur ILS localizer course extending from the 6.8-mile radius to 7 miles south of the airport.

* * * * *

Issued in Kansas City, MO, on August 29, 1997.

Christopher R. Blum,

Acting Manager, Air Traffic Division, Central Region.

[FR Doc. 97–27362 Filed 10–16–97; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 97–AMN–6]

Establishment of Class E Airspace; Driggs, ID

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Direct final rule; confirmation of effective date.

SUMMARY: The direct final rule published on June 17, 1997 (62 FR 32683), establishes Class E airspace at Teton Peaks/Driggs Municipal Airport, Driggs, ID. This action also amends the Idaho Falls, ID, 1,200-foot Class E airspace area. The effect of that rule is to provide adequate controlled airspace for a new Global Positioning System (GPS–A) approach procedure to Teton Peaks/Driggs Municipal Airport. This document confirms the effective date of that rule.

EFFECTIVE DATE: The direct final rule published at 62 FR 32683 is effective 0901 UTC, November 1, 1997.

FOR FURTHER INFORMATION CONTACT: James Riley, ANM–520.4, Federal Aviation Administration, 1601 Lind Avenue S.W., Renton, Washington 98055–4056; telephone number: (425) 227–2537.

SUPPLEMENTARY INFORMATION: The FAA published the direct final rule with a request for comments in the **Federal Register** on June 17, 1997 (62 FR 32683).

The FAA uses the direct final rulemaking procedure for a non-controversial rule where the FAA believes that there will be no adverse public comment. This direct final rule advised the public that no adverse comments were anticipated, and that unless a written adverse comment, or a written notice of intent to submit such an adverse comment, were received within the comment period, the regulation would become effective on November 1, 1997. No adverse comments were received, and thus this document confirms that the final rule will become effective on that date.

Issued in Seattle, Washington, on September 9, 1997.

Glenn A. Adams III,

Assistant Manager, Air Traffic Division, Northwest Mountain Region.

[FR Doc. 97–27395 Filed 10–16–97; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 97–AGL–26]

Modification of Class E Airspace; French Lick, IN

AGENCY: Federal Agency Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action modifies Class E airspace at French Lick, IN. A Nondirectional Beacon (NDB) Standard Instrument Approach Procedure (SIAP) to Runway (RWY) 8 has been developed for French Lick Municipal Airport. Controlled airspace extending upward from 700 to 1200 feet above ground level (AGL) is needed to contain aircraft executing the approach. This action adds a southwest extension to the existing controlled airspace. The intended effect of this action is to provide segregation of aircraft using instrument approach procedures in instrument conditions from other aircraft operating in visual weather conditions.

EFFECTIVE DATE: 0901 UTC, January 1, 1998.

FOR FURTHER INFORMATION CONTACT:

Michelle M. Behm, Air Traffic Division, Airspace Branch, AGL–520, Federal Agency Administration, 2300 East Devon Avenue, Des Plaines, Illinois 60018, telephone (847) 294–7568.

SUPPLEMENTARY INFORMATION:

History

On Friday, July 25, 1997, the FAA proposed to amend part 71 of the Federal Aviation Regulations (14 CFR part 71) to modify Class E airspace at French Lick, IN (62 FR 39978). The proposal was to add controlled airspace extending upward from 700 to 1200 feet AGL to contain Instrument Flight Rules (IFR) operations in controlled airspace during portions of the terminal operation and while transiting between the enroute and terminal environments.

Interested parties were invited to participate in this rule proceeding by submitting written comments on the proposal to the FAA. No comments objecting to the proposal were received. One comment supporting the proposal was received. Class E airspace designations for airspace areas extending upward from 700 feet or more above the surface of the earth are published in paragraph 6005 of FAA Order 7400.9E, dated September 10, 1997, and effective September 16, 1997, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document will be published subsequently in the Order.

The Rule

This amendment to part 71 of the Federal Aviation Regulations (14 CFR part 71) modifies Class E airspace at French Lick, IN, to accommodate aircraft executing the NDB RWY 8 SIAP at French Lick Municipal Airport. Controlled airspace extending upward from 700 to 1200 feet AGL is needed to contain aircraft executing the approach. The area will be depicted on appropriate aeronautical charts.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this regulation—(1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Agency Administration amends 14 CFR part 71 as follows:

PART 71—[AMENDED]

1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9E, Airspace Designations and Reporting Points, dated September 10, 1997, and effective September 16, 1997, is amended as follows:

Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.

* * * * *

AGL IN E5 French Lick, IN [Revised]

French Lick Municipal Airport, IN
(Lat. 38°30′22″ N, long. 86°38′13″ W)
Oranj NDB
(Lat. 38°31′40″ N, long. 86°31′40″ W)

That airspace extending upward from 700 feet above the surface within a 6.5-mile radius of the French Lick Municipal Airport, and within 5.9 mile either side of the 255° bearing from the Oranj NDB extending from the 6.5-mile radius area to 6.9 miles southwest of the airport.

* * * * *

Issued in Des Plaines, Illinois on September 15, 1997.

Maureen Woods,

Manager, Air Traffic Division.

[FR Doc. 97–27393 Filed 10–16–97; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. 97–ACE–13]

Amendment to Class E Airspace, Vinton, IA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Direct final rule; request for comments.

SUMMARY: This action amends the Class E airspace area at Vinton Veterans Memorial Airpark, Vinton, IA. The FAA has developed Standard Instrument

Approach Procedures (SIAPs) to Runway (RWY) 9 and RWY 27 based on the Global Positioning System (GPS) to serve the Vinton Veterans Memorial Airpark, Vinton, IA. The intended effect of this action is to provide additional controlled airspace extending upward from 700 feet Above Ground level (AGL) to accommodate these SIAPs and to provide segregation for aircraft using instrument approach procedures in instrument conditions from aircraft operating in visual weather conditions at the Vinton Veterans Memorial Airpark.

DATES: *Effective date.* 0901 UTC, February 26, 1998. *Comment date.* Comments must be received on or before November 15, 1997.

ADDRESSES: Send comments regarding the rule in triplicate to: Manager, Airspace Branch, Air Traffic Division, ACE–520, Federal Aviation Administration, Docket Number 97–ACE–13, 601 East 12th St., Kansas City, MO 64106.

The official docket may be examined in the Office of the Assistant Chief Counsel for the Central Region at the same address between 9:00 a.m. and 3:00 p.m., Monday through Friday, except Federal holidays.

An informal docket may also be examined during normal business hours in the Air Traffic Division at the same address listed above.

FOR FURTHER INFORMATION CONTACT:

Kathy Randolph, Air Traffic Division, Airspace Branch, ACE–520C, Federal Aviation Administration, 601 East 12th Street, Kansas City, Missouri 64106; telephone: (816) 426–3408.

SUPPLEMENTARY INFORMATION: The FAA has developed SIAPs utilizing the GPS to serve the Vinton Veterans Memorial Airpark, Vinton, IA. The amendment to Class E airspace at Vinton Veterans Memorial Airpark, IA, is necessary to provide additional controlled airspace at and above 700 feet AGL to contain the new SIAPs within controlled airspace and thereby facilitate separation of aircraft operating under instrument flight rules (IFR). The area will be depicted on appropriate aeronautical charts. Class E airspace areas extending from 700 feet or more above the surface of the earth are published in paragraph 6005 of FAA Order 7400.9E, dated September 10, 1997, and effective September 16, 1997, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document will be published subsequently in the Order.

The Direct Final Rule Procedure

The FAA anticipates that this regulation will not result in adverse or negative comment and, therefore, is issuing it as a direct final rule. Previous actions of this nature have not been controversial and have not resulted in adverse comments or objections. The amendment will enhance safety for all flight operations by designating an area where VFR pilots may anticipate the presence of IFR aircraft at lower altitudes, especially during inclement weather conditions. A greater degree of safety is achieved by depicting the area on aeronautical charts. Unless a written adverse or negative comment, or a written notice of intent to submit an adverse or negative comment is received within the comment period, the regulation will become effective on the date specified above. After the close of the comment period, the FAA will publish a document in the **Federal Register** indicating that no adverse or negative comments were received and confirming the date on which the final rule will become effective. If the FAA does receive, within the comment period, an adverse or negative comment, or written notice of intent to submit such a comment, a document withdrawing the direct final rule will be published in the **Federal Register**, and a notice of proposed rulemaking may be published with a new comment period.

Comments Invited

Although this action is in the form of a final rule and was not preceded by a notice of proposed rulemaking, comments are invited on this rule. Interested persons are invited to comment on this rule by submitting such written data, views, or arguments as they may desire. Communications should identify the Rules Docket number and be submitted in triplicate to the address specified under the caption **ADDRESSES**. All communications received on or before the closing date for comments will be considered, and this rule may be amended or withdrawn in light of the comments received. Factual information that supports the commenter's ideas and suggestions is extremely helpful in evaluating the effectiveness of this action and determining whether additional rulemaking action would be needed.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy-related aspects of the rule that might suggest a need to modify the rule. All comments submitted will be available, both before and after the closing data for comments, in the Rules Docket for examination by interested persons. A report that summarizes each FAA-public contact concerned with the substance of this action will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this rule must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. 97–ACE–13.'' The postcard will be date stamped and returned to the commenter.

Agency Findings

The regulations adopted herein will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

The FAA has determined that this regulation is noncontroversial and unlikely to result in adverse or negative comments. For the reasons discussed in the preamble, I certify that this regulation (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under Department of Transportation (DOT) Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air)

Adoption of the Amendment

Accordingly, the Federal Aviation Administration amends Part 71 of the Federal Aviation Regulations (14 CFR Part 71) as follows:

PART 71—DESIGNATION OF CLASS A, CLASS B, CLASS C, CLASS D, AND CLASS E AIRSPACE AREAS; AIRWAYS; ROUTES; AND REPORTING POINTS

1. The authority citation for Part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation

Administration Order 7400.9E, Airspace Designations and Reporting Points, dated September 10, 1997, and effective September 16, 1997, is amended as follows:

Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.

* * * * *

ACE IA E5 Vinton, IA [Revised]

Vinton Veterans Memorial Airpark, IA
(Lat. 42°13′03″ N., long 92°01′44″ W.)

That airspace extending upward from 700 feet above the surface within a 6.5-mile radius of Vinton Veterans Memorial Airpark.

* * * * *

Issued in Kansas City, MO, on August 29, 1997.

Christopher R. Blum,

Acting Manager, Air Traffic Division, Central Region.

[FR Doc. 97–27380 Filed 10–16–97; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 97–AEA–18]

Establishment of Class E Airspace; Marion, VA; Correction

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; correction.

SUMMARY: This action corrects an error in the airspace description of a final rule that was published in the **Federal Register** on May 23, 1997 (62 FR 28335), Airspace Docket No. 97–AEA–18. The final rule established Class E airspace at Marion, VA.

EFFECTIVE DATE: October 17, 1997.

FOR FURTHER INFORMATION CONTACT:

Michael J. Sammartino, Air Traffic Division, Operations Branch, AEA–530, Federal Aviation Administration, Federal Building, #111, John F. Kennedy Int'l Airport, Jamaica, NY 11430; telephone: (718) 553-4530.

SUPPLEMENTARY INFORMATION:

History

Federal Register document 97–13581, Airspace Docket 97–AEA–18, published on May 23, 1997 (62 FR 28335), established the Class E airspace at Marion, VA. An error was discovered in the coordinates of the airspace description. This action corrects that error.

Correction to Final Rule

Accordingly, pursuant to the authority delegated to me, the airspace description for the Marion, VA, Class E airspace area, incorporated by reference in § 71.1, as published in the **Federal Register** on May 23, 1997 (62 FR 28335), (**Federal Register** Document 97–13581) is corrected as follows:

§ 71.1 [Corrected]

On page 28336, column 1, the airspace description for Marion, VA, is corrected to read as follows:

* * * * *

AEA VA E5 Marion, VA [Corrected]

Mountain Empire Airport,
Marion/Wytheville, VA
(Lat. 36°53′41″ N., long 81°21′00″ W.)

That airspace extending upward from 700 feet above the surface within a 10-mile radius of Mountain Empire Airport and within 8 miles north and 4 miles south of the 073° bearing from the airport extending from the 10-mile radius to 16 miles northeast of the airport.

* * * * *

Issued in Jamaica, New York, on September 16, 1997.

Franklin D. Hatfield,

Manager, Air Traffic Division, Eastern Region.

[FR Doc. 97–27396 Filed 10–16–97; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 97–AEA–002]

Establishment of Class E Airspace; East Butler, PA; Correction

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; correction.

SUMMARY: This action corrects an error in the airspace description of a final rule that was published in the **Federal Register** on May 23, 1997, Airspace Docket No. 96–AEA–002. The final rule established Class E airspace at East Butler, PA.

EFFECTIVE DATE: October 17, 1997.

FOR FURTHER INFORMATION CONTACT:

Michael J. Sammartino, Air Traffic Division, Operations Branch, AEA–530, Federal Aviation Administration, Federal Building #111, John F. Kennedy Int'l Airport, Jamaica, NY 11430; telephone: (718) 553–4530.

SUPPLEMENTARY INFORMATION:

History

Federal Register document 97–13585, Airspace Docket 97–AEA–002, published on May 23, 1997 (62 FR 28333), established the Class E airspace at East Butler, PA. An error was discovered in the airport name in the airspace description exclusion areas. This action corrects that error.

Correction to Final Rule

Accordingly, pursuant to the authority delegated to me, the airspace description for the East Butler Class E airspace area, incorporated by reference in § 71.1, as published in the **Federal Register** on May 23, 1997 (62 FR 28333), (**Federal Register** Document 97–13585) is corrected as follows:

§ 71.1 [Corrected]

On page 28334, column 1, the airspace description for East Butler, PA, is corrected to read as follows:

* * * * *

AEA PA E5 East Butler, PA [Corrected]

Butler Memorial Hospital Heliport, PA
Point In Space Coordinates
(Lat. 40°51′19″ N., long. 79°51′51″ W.)

That airspace extending upward from 700 feet above the surface within a 6-mile radius of the Point In Space serving Butler Memorial Hospital Heliport, excluding that portion that coincides with the Butler, PA, Class E airspace area.

* * * * *

Issued in Jamaica, New York, on September 16, 1997.

Franklin D. Hatfield,

Manager, Air Traffic Division, Eastern Region.

[FR Doc. 97–27502 Filed 10–16–97; 8:45 am]

BILLING CODE 4910–13–M

SECURITIES AND EXCHANGE COMMISSION

17 CFR Parts 230 and 240

[Release Nos. 33–7470 and 34–39227; S7–26–96]
[International Series Release No. 1103]

RIN 3235–AG85

Offshore Press Conferences, Meetings with Company Representatives Conducted Offshore and Press-Related Materials Released Offshore

AGENCY: Securities and Exchange Commission.

ACTION: Final Rules.

SUMMARY: The Commission is adopting two safe harbors designed to facilitate U.S. press access to offshore press activities. The two safe harbors will clarify the conditions under which journalists may be provided access to offshore press conferences, offshore meetings and press materials released offshore, in which a present or proposed

offering of securities or tender offer is discussed, without violating the provisions of Section 5 of the Securities Act of 1933, or the procedural requirements of the tender offer rules promulgated under the Williams Act.

EFFECTIVE DATE: The rule and amendments will become effective November 17, 1997.

FOR FURTHER INFORMATION CONTACT: Felicia H. Kung, Office of International Corporate Finance, Division of Corporation Finance, at (202) 942–2990.

SUPPLEMENTARY INFORMATION: The Commission is adopting a safe harbor with respect to the registration requirements of the Securities Act of 1933 (''Securities Act'')[1] to permit a foreign private issuer or foreign government issuer, selling security holder or their representatives to provide any journalist, whether foreign or domestic, with access to press conferences held outside the United States, to meetings with issuer or selling security holder representatives conducted outside the United States, or to press-related materials released outside the United States, at or in which a present or proposed offering of securities is discussed (''Securities Act safe harbor''). The safe harbor would clarify that providing press access under the safe harbor would not be deemed an ''offer'' for the purposes of Section 5[2] of the Securities Act;[3] ''directed selling efforts'' within the meaning of Regulation S[4] under the Securities Act; or a ''general solicitation'' within the meaning of Regulation D[5] under the Securities Act. The Commission also is adopting a safe harbor whereby a bidder for the securities of a foreign private issuer, as well as the subject company, their representatives, or any other person specified in Rule 14d–9(d)[6] under the Securities Exchange Act of 1934 (''Exchange Act''), will not be subject to the filing and procedural requirements of Regulations 14D[7] and 14E[8] under the Exchange Act by virtue of providing any journalist, whether foreign or domestic, with access to its press conferences held outside the United States, to meetings with its representatives conducted outside the United States, or to press-related materials released outside the United States, at or in which a present or proposed tender offer is discussed (''Tender Offer safe harbor'').

I. Background

U.S. journalists are being excluded on a regular basis from the offshore press activities of foreign issuers.[9] This practice may not foster the interests of U.S. investors, since the information is made available to U.S. press shortly following the release of the information offshore. Instead, the practice is both anti-competitive and potentially disadvantageous to U.S. investors by delaying their access to information made immediately available to investors offshore. The purpose of this rulemaking is to eliminate this unintended and undesirable consequence of the Commission's rules governing offering publicity.

The Commission published for comment in October 1996 proposed safe harbors to facilitate U.S. press access to offshore press activities conducted by issuers, selling security holders and their representatives (''Proposing Release'').[10]

The Commission proposed these safe harbors in recognition of the difficulties faced by journalists for publications with significant U.S. circulation in gaining direct access to offshore press activities in which a present or proposed offering of securities or tender offer is discussed. Many issuers have denied these journalists access to offshore press conferences, offshore meetings with company representatives and press materials released offshore that pertain to a present or proposed securities offering or tender offer out of concern that this access would result in a violation of the U.S. federal regulatory requirements for these offerings. Past rulemaking and interpretive guidance by the Commission and its staff do not appear to have allayed the concerns of companies conducting offshore press activities, and U.S. press continue to be denied access to offshore press activities even when no U.S. offering is contemplated.

The U.S. Congress has also been aware of this exclusion. In the National Securities Markets Improvement Act of 1996,[11] Congress directed the Commission to conduct rulemaking to clarify the status of offshore press activities under the Securities Act.

After reviewing the thirteen comment letters received on the proposed safe harbors and further considering the proposals,[12] the Commission is adopting the safe harbors substantially as proposed with one significant modification. The Securities Act safe harbor as adopted will not be available to U.S. issuers.[13] Although the Commission initially had proposed making that safe harbor available to both foreign and domestic issuers, the Commission has determined that relief is unnecessary with respect to U.S. issuers and that it may be preferable to address publicity in connection with offerings by U.S. issuers in a more comprehensive fashion.

Some foreign jurisdictions, unlike the United States, permit companies that are offering securities to conduct press conferences, issue press releases, and meet with members of the press during the offering as a means of publicizing the offering. Foreign issuers adopting those practices are unlikely to be doing so for the purpose of circumventing U.S. restrictions on publicity. On the other hand, extending the safe harbor to U.S. issuers that have not traditionally employed such practices in the offering of securities unnecessarily invites that potential for abuse. In addition, the Commission understands that the difficulty experienced by the U.S. press in obtaining access to foreign press activities is most significant with respect to foreign issuers.[14] Accordingly, by excluding U.S. issuers from the Securities Act safe harbor, the Commission is crafting a narrow approach that addresses the concerns of the U.S. press by accommodating the anomalies that can result when offshore offering practices differ from what is permitted in the United States, yet allows the Commission to consider crafting a regulatory approach with respect to U.S. issuers in a comprehensive fashion both with respect to offshore and domestic press activities.

The Commission may reconsider the safe harbor adopted today at a later date in light of its ongoing reexamination of

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[1] 15 U.S.C. 77a *et seq.*

[2] 15 U.S.C. 77e.

[3] 17 CFR 230.135e.

[4] 17 CFR 230.901 through 17 CFR 230.904 and Preliminary Notes.

[5] 17 CFR 230.501 through 17 CFR 230.508 and Preliminary Notes.

[6] 17 CFR 240.14d–9.

[7] 17 CFR 240.14d–1 through 17 CFR 240.14d–10.

[8] 17 CFR 240.14e–1 through 17 CFR 240.14e–2.

[9] *See SEC Rules Not OK*, EUROMONEY, July 1997, at 64.

[10] Release No. 33–7356 (Oct. 10, 1996) [61 FR 54518].

[11] Pub. L. No. 104–290, 110 Stat. 3416 (1996) (codified in scattered sections of the United States Code).

[12] The comment letters are available for inspection and copying in the Commission's public reference room. Refer to file number S7–26–96. Comment letters that were submitted via electronic mail may be viewed at the Commission's web site: http://www.sec.gov.

[13] In contrast, the Tender Offer safe harbor will be available to both U.S. and foreign bidders as long as the target company qualifies as a foreign private issuer.

[14] *See supra* note 9. *See also* Roberta S. Karmel & Mary S. Head, *Barriers to Foreign Issuer Entry into U.S. Markets; Symposium on Managing Economic Interdependence*, 24 LAW & POL'Y INT'L BUS. 1207 (1993).

the Commission's regulation of securities offerings under the Securities Act and the rules thereunder. In July 1996, the Commission issued a Securities Act Concept Release (''Concept Release'') [15] that reviewed the current regulatory framework for securities offerings, particularly with respect to regulating publicity in connection with a securities offering. The Concept Release suggested a number of alternative approaches and solicited comments from the public. Many commenters recognized that this wide-ranging examination of the permissible level of publicity in connection with securities offerings is fundamental to the Commission's administration of the Securities Act. On the other hand, they urged that the practice of excluding the U.S. press from foreign press activities itself presents ongoing significant policy concerns that should and can be addressed in a narrow and expeditious fashion.

II. Securities Act Safe Harbor

A. General

The Commission is adopting Rule 135e under the Securities Act to provide a safe harbor for offshore press activities conducted in connection with an offering by a foreign private issuer or foreign government issuer.[16] Under the Securities Act safe harbor, a foreign private issuer or foreign government issuer, selling security holder, or their representatives may provide foreign and U.S. journalists [17] with access to offshore press conferences, meetings with issuer or selling security holder representatives conducted offshore, or press-related materials released offshore without being viewed as making an ''offer'' for purposes of Section 5 of the Securities Act as long as certain conditions enumerated below are satisfied. Press activities that are covered by the Securities Act safe harbor also would not constitute a general solicitation or general advertising within the meaning of Regulation D, or ''directed selling efforts'' within the meaning of Regulation S. The Commission is adopting amendments to Rule 502 [18] of Regulation D and Rule 902 [19] of Regulation S [20] to reflect this.

As adopted, the safe harbor will apply to all foreign private issuers and foreign governments regardless of whether these issuers file periodic Exchange Act reports with the Commission. In addition, representatives of the issuer and the selling security holders, such as underwriters and public relations firms, may rely on the safe harbor, although persons with no relationship to the issuer are excluded from the safe harbor.

As in the proposal, the safe harbor does not cover paid advertisements. The Commission also noted in the Proposing Release that analysts' research reports would not be covered, since Securities Act Rules 138 [21] and 139 [22] cover those reports. Several commenters opposed the exclusion of analysts' reports from the Securities Act safe harbor because these reports are often distributed as part of the offshore offering process. However, the Commission did not intend that providing research reports in written press-related materials would cause any materials included in the press package, including analysts' research reports, to lose safe harbor protection. To clarify, analysts' research reports would be covered by the new safe harbor (even if Rules 138 and 139 are not available) to the same extent, and under the same conditions, as other written materials in the package.[23]

The safe harbor only applies to the Section 5 registration requirements of the Securities Act. The scope of the antifraud or other provisions of the federal securities laws, including Sections 12(a)(2) [24] and 17(a) [25] of the Securities Act, that relate to both oral and written material misstatements and omissions in the offer and sale of securities will not be affected by the safe harbor.

B. Conditions to the Safe Harbor

The Securities Act safe harbor is available only if the conditions described below are satisfied. These conditions are intended to minimize the possibility that issuers may use the safe harbor to circumvent important Securities Act protections.

The safe harbor as adopted is a purely objective test. All of the nine commenters who addressed the desirability of an objective test supported that approach. Many of them believed that a subjective test would result in the continued exclusion of U.S. press from offshore press activities. In addition, commenters noted that the antifraud and civil liability provisions of the federal securities laws should provide adequate protection to investors.

1. Press Activity Must Occur Offshore

The press activities that are covered by the safe harbor must occur outside of the United States.[26] To come under the safe harbor, a press conference or meeting with issuer or selling security holder representatives must be conducted outside the United States, and any press-related materials must be released outside of the United States. Under this approach, the journalist to whom access is provided must receive any written press-related materials at a physical location and address that is offshore. In addition, conference calls in which at least one of the participants is located in the United States would not be covered by the safe harbor.

Follow-up press contacts in which the journalist (whether foreign or U.S.) is located in the United States at the time of the follow-up are not included in the safe harbor. As one of the commenters pointed out, this should not be a problem in most cases, since journalists who attend offshore press conferences typically are based offshore. As this commenter stated in its letter:

> We do not believe follow-up conversations [citation omitted] present a major issue because in most cases we believe journalists based offshore will be attending the offshore press conferences rather than U.S. residents travelling to another country. Attempting to cover follow-up conversations or other communications where one party is in the United States would pose an unnecessary complication for operation of the safe harbor.[27]

This approach is consistent with the limited goal of accommodating different offering practices followed in the issuer's home jurisdiction to avoid exclusion of U.S. press from those

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[15] Release No. 33–7314 (July 25, 1996) [61 FR 40044].

[16] ''Foreign private issuer'' is defined in Securities Act Rule 405 [17 CFR 230.405] and Exchange Act Rule 3b–4(c) [17 CFR 240.3b-4(c)].

[17] Consistent with the recommendation of commenters, the safe harbor does not provide a definition of ''journalist.'' In response to questions by commenters, the Commission notes that it views on-line services and independent free-lance writers as bona fide ''journalists'' under both the Securities Act safe harbor and Tender Offer safe harbor.

[18] 17 CFR 230.502.

[19] 17 CFR 230.902.

[20] Preliminary Note 7 of Regulation S is being amended to clarify the relationship of that general statement to the Securities Act safe harbor and Tender Offer safe harbor.

[21] 17 CFR 230.138.

[22] 17 CFR 230.139.

[23] The application of Section 5 of the Securities Act to the publication of analysts' reports by analysts themselves, rather than by an issuer or selling security holder, will continue to be considered separately under Rules 138 and 139 under the Securities Act.

[24] 15 U.S.C. 77l(a)(2).

[25] 15 U.S.C. 77q(a).

[26] For clarification, a definition of ''United States'' has been included in Rule 135e that is the same as the definition used in Rule 902(p) of Regulation S [17 CFR 230.902(p)]. ''United States'' is defined to include the United States of America, its territories and possessions, as well as the individual states of the United States and the District of Columbia.

[27] Comment letter from Dow Jones & Company, Inc. of 12/17/96, at p. 5.

activities. This also is consistent with the general territorial approach used in the application of the Securities Act registration requirements.[28]

2. Offshore Offering

As a condition to the safe harbor, the offering must not occur solely within the United States. This condition reflects the Commission's concern that an issuer not conduct press activities solely to ''condition the market'' in the United States for the issuer's securities. There is a far greater likelihood that offshore publicity with respect to offerings that are made exclusively in the United States is intended for that purpose.

Some commenters urged the Commission to include U.S.-only offerings in the Securities Act safe harbor. They noted that these offerings may be newsworthy events in the home jurisdictions of foreign issuers, and that certain foreign jurisdictions may even require disclosure of these offerings. Rules 134,[29] 135[30] and 135c[31] under the Securities Act should provide adequate protection for issuers giving notice of offerings. In addition, even if the new safe harbor and Rules 134, 135 and 135c do not cover the press activities for U.S.-only offerings of foreign issuers, this does not necessarily mean that allowing U.S. press access would cause a Section 5 violation. Instead, that question would depend on an analysis of all the facts and circumstances.[32]

The condition that at least part of the offering be made offshore does not impose any requirement that a specific amount be offered offshore. The commenters that addressed this issue strongly supported this approach. Commenters noted that requiring a specific minimum portion of the offering to take place offshore would undercut the benefit of the safe harbor. Because issuers may not know how much of an offering will be made offshore, this uncertainty could lead them to exclude journalists from offshore press activities unnecessarily. There must, however, be an intent to make a bona fide offering offshore; the mere offering of a token amount will not suffice to bring the transaction within the safe harbor. Should the Commission become aware of abuses involving offerings that do not appear to include a bona fide offshore component, it will revisit the rule to consider imposing a stricter, more objective standard.

3. Access Provided to Both U.S. and Foreign Journalists

Another condition of the safe harbor is that the offshore press activity must be available to foreign journalists, as well as to U.S. journalists. The safe harbor would not be available if *only* U.S. journalists were permitted to attend the offshore press activity or to receive the offshore press-related materials. This minimizes the possibility that the safe harbor would be used to channel publicity regarding the offering solely into the United States. Foreign journalists must have the same access to the offshore press activity or materials, although the safe harbor does not require the issuer to monitor whether foreign journalists actually attend the offshore press activity or actually receive the offshore press-related materials for the safe harbor to apply. The Commission has determined that the actual attendance or receipt of materials by foreign journalists is beyond the issuer's control, and that a monitoring requirement would be too burdensome.

In the Proposing Release, the Commission indicated that it would view ''one-on-one'' interviews with a U.S. journalist as covered by the safe harbor. However, if the ''one-on-one'' meeting was conducted on an ''exclusive'' basis with a purely ''U.S. publication'' and no other ''one-on-one'' interviews with other foreign publications were given, the Commission expressed its concern that the exclusive ''one-on-one'' presentation might signal a scheme to channel publicity regarding the offering into the United States. Nonetheless, the Commission indicated in the Proposing Release that if an issuer or its representatives conducts a press conference that complies with the requirements of the safe harbor (*e.g.*, where both U.S. and foreign journalists are allowed to attend) either before or after the exclusive ''one-on-one'' meeting with a purely domestic publication,[33] the Commission would view the exclusive interview as covered by the safe harbor. A few commenters objected to this interpretation as unduly restrictive and unnecessary.[34] However, the Commission continues to believe that there is a real basis for concern that the exclusive ''one-on-one'' would be used solely to channel publicity into the United States, absent an offshore press conference or other foreign press activity conducted in connection with an offering.

4. Written Materials Requirements

Written materials that are released to journalists under the safe harbor present special concerns, especially if the materials are released with respect to an offering that is likely to be of significant interest to U.S. investors. The Commission is concerned that materials may result in offers of securities in the United States without the protections of the federal securities laws, or in conditioning the market in the United States for the securities to be offered. To address these concerns, the Commission proposed additional procedural safeguards to be imposed on written materials released to journalists. These safeguards were intended to alert recipients that such materials should not be considered an offer of securities for sale in the United States, and that when and if an offer is made in the United States, the appropriate required disclosure would be disseminated at that time.

The Commission is adopting the ''Written Materials Requirements'' substantially as proposed.[35] These requirements must be met whenever written materials released under the safe harbor discuss an offering of securities by any foreign private issuer and foreign government where part of the offering is or will be conducted in the United States. The requirements apply irrespective of whether the U.S. portion of the offering is registered or exempt. However, consistent with the Proposing Release, the ''Written Materials Requirements'' will not be imposed on securities offerings of foreign private issuers and foreign governments that are offered and sold wholly offshore because those offerings would appear to be of less significant interest to U.S. investors.

The ''Written Materials Requirements'' are as follows:

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[28] *See* Rule 901 of Regulation S [17 CFR 230.901].

[29] 17 CFR 230.134.

[30] 17 CFR 230.135.

[31] 17 CFR 230.135c.

[32] Preliminary Note 7 to Regulation S should continue to provide guidance in that instance.

[33] The Commission does not believe that the press conference must be conducted within any particular time frame. In the Commission's view, a press conference held in connection with the offering would be sufficient evidence that the exclusive ''one-on-one'' was not an attempt to condition the U.S. markets.

[34] Some commenters opposed the press conference requirement for purely domestic publications as unnecessary for legitimate news coverage. *See* comment letter from Bloomberg L.P. of 12/17/96, at p. 8, and comment letter from Sullivan & Cromwell of 12/20/96, at p. 13.

[35] As originally proposed, the ''Written Materials Requirements'' were required to be satisfied whenever the written materials discussed an offering of securities by a U.S. issuer. Because U.S. issuers will not be covered by the safe harbor, as initially contemplated in the Proposing Release, the ''Written Materials Requirements'' have been modified to reflect this.

1. The materials must include a statement that the materials are not an offer of securities for sale in the United States; that the securities may not be offered or sold in the United States unless they are registered or exempt from registration; and that any public offering of securities to be made in the United States will be made by means of a prospectus that will contain detailed information about the company and management, as well as financial statements. In addition, if any portion of the offering will be registered in the United States, the materials must include a legend stating this intention.

2. The issuer or selling security holder cannot attach to, or otherwise make a part of, the written materials any form of purchase order or coupon that could be returned indicating interest in the offering.

Several commenters objected to certain aspects of the ''Written Materials Requirements,'' most notably the legending requirements and the coupon prohibition. They contended that these requirements would make the safe harbor difficult to apply without improving investor protection. Nonetheless, the Commission believes that these requirements significantly reduce the possibility that written materials released to U.S. journalists, and that may come into the hands of U.S. investors, will be used to offer securities in the United States without the protections of the U.S. securities laws. Since the requirements are only imposed when the issuer is otherwise required to meet U.S. offering regulations because a portion of the offering is to be made in the United States, the requirements are not unduly burdensome and the possibility of inadvertent violations is minimal.

III. Tender Offer Safe Harbor

A. General

The Commission is adopting the Tender Offer safe harbor as proposed. The safe harbor is only available with respect to a target company that is a foreign private issuer,[36] and is narrowly crafted to permit both the bidder and foreign target to conduct their activities in a manner consistent with local offering practices. Pursuant to Rule 14d-1 under the Exchange Act, [37] as amended, a bidder for the securities of a foreign private issuer, as well as the foreign target company, the representatives of either and any other person who may have a filing obligation under the Williams Act would not be deemed to have triggered the filing and procedural requirements of the Williams Act [38] by virtue of providing U.S. or foreign journalists with access to offshore press conferences, offshore meetings with representatives, and press-related materials released offshore, at or in which a present or proposed tender offer of securities is discussed.[39] Although the safe harbor will be available to either a U.S. or a foreign bidder, the safe harbor will only be applicable if the target company is a foreign private issuer. The safe harbor will not be available for the securities of a U.S. target issuer because there appears to be no need to accommodate foreign offering practices in that instance.

The safe harbor only affects the triggering of the filing and procedural requirements of the Williams Act, and would not affect the scope or applicability of the antifraud prohibition of Section 14(e) [40] of the Exchange Act, or the prohibition against trading on material nonpublic information regarding a tender offer in Rule 14e–3[41] under the Exchange Act.

The purpose of the Tender Offer safe harbor is to prevent the application of the U.S. tender offer rules before a bidder is prepared to proceed with the offer. After an offer has commenced with the filing of documents with the Commission under Regulation 14D, the safe harbor would not be available.

B. Conditions

The applicability of the Tender Offer safe harbor is subject to several conditions that are analogous to the Securities Act safe harbor conditions. Both U.S. and foreign journalists must have access to the offshore press activity, and the written materials that are covered by the safe harbor must be appropriately legended in circumstances where significant U.S. investor interest in the tender offer is likely. In addition, no means to tender securities, or coupons that could be returned to indicate interest in the tender offer may be provided as part of any press-related materials.

If the present or proposed tender offer described in the written materials released under the proposed tender offer safe harbor is for equity securities registered under Section 12 [42] of the Exchange Act, the materials must comply with certain requirements (''Written Materials Requirements'').[43] These requirements are as follows:

1. The materials must include a statement that the materials are not an extension of the tender offer in the United States for a class of equity securities of the subject company. In addition, if the bidder intends to extend the tender offer in the United States at some future time for a class of equity securities of the subject company, the materials must include a legend stating this intention and stating that the procedural and filing requirements of the Williams Act will be satisfied at that time.

2. No means to tender securities, or coupons that could be returned to indicate interest in the tender offer may be provided as part of, or attached to, any press-related materials.

IV. Certain Findings

Section 23(a) of the Exchange Act [44] requires the Commission to consider the anti-competitive effects of any rules it adopts thereunder, if any, and the reasons for its determination that any burden on competition imposed by such rules is necessary or appropriate to further the purposes of the Exchange Act. Furthermore, Section 2 [45] of the Securities Act and Section 3 [46] of the Exchange Act, as amended by the National Securities Markets Improvement Act of 1996,[47] provide that whenever the Commission is engaged in rulemaking and is required to consider or determine whether an action is necessary or appropriate in the public interest, the Commission also shall consider, in addition to the protection of investors, whether the action will

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[36] Several commenters objected to this limited application of the safe harbor. They noted, among other things, that bidders may have difficulty ascertaining whether a target company qualifies as a foreign private issuer. However, the Commission has determined that the safe harbor is easiest to apply if a foreign private issuer definition is used. A bidder may presume that a target company qualifies as a ''foreign private issuer'' if the target company is a foreign issuer that files registration statements with the Commission on the disclosure forms specifically designated for foreign private issuers (such as Form F–1 or Form 20–F), claims the exemption from Exchange Act registration pursuant to Exchange Act Rule 12g3–2(b) [17 CFR 240.12g3–2(b)], or is not reporting in the United States.

[37] 17 CFR 240.14d–1.

[38] Offshore press activity during a tender offer would not trigger the following requirements: Section 14(d)(1) [15 U.S.C. 78n(d)(1)] through Section 14(d)(7) [15 U.S.C. 78n(d)(7)] of the Exchange Act, Regulation 14D [17 CFR 240.14d–1 through 17 CFR 240.14d–10), and Rules 14e–1 [17 CFR 240.14e–1] and 14e–2 [17 CFR 240.14e–2].

[39] The Tender Offer safe harbor, however, would not exempt from the Securities Act registration requirements exchange offers in which a U.S. bidder is involved.

[40] 15 U.S.C. 78n(e).

[41] 17 CFR 240.14e-3.

[42] 15 U.S.C. 78*l*.

[43] As with the Written Materials Requirements under the Securities Act safe harbor, some commenters objected to the legending and coupon conditions of the Tender Offer safe harbor. The Commission believes that these conditions reduce the possibility that the Tender Offer safe harbor will be used to circumvent the protections provided by the federal securities laws. The Written Materials Requirements do not apply where those protections are not applicable, including in the case of tender offers for a class of equity securities that is not registered with the Commission, or tender offers for debt securities.

[44] 15 U.S.C. 78w(a).

[45] 15 U.S.C. 77b.

[46] 15 U.S.C. 78c.

[47] Pub. L. No. 104–290, § 106, 110 Stat. 3416 (1996).

promote efficiency, competition, and capital formation.

The Commission has considered the rule and amendments discussed in this release in light of the comments received in response to the Proposing Release and the standards in Section 23(a) of the Exchange Act. The rule and amendments are intended to reduce anti-competitive barriers between U.S. and foreign journalists. As a result of the rule and amendments, U.S. journalists will have increased access to offshore press activities conducted by issuers and selling security holders and, in the case of tender offers, by bidders for foreign private issuers, as well as the foreign target company itself. Although some of the requirements under the safe harbors, such as the legending requirements and coupon prohibition, may place certain burdens on those who wish to rely on the safe harbors, the overall effect of the safe harbors is to decrease anti-competitive barriers. Without the safe harbors, U.S. press will continue to be excluded from the offshore press activities of foreign issuers. This may harm U.S. investors because they eventually receive the information disseminated offshore, but on a delayed basis. With the safe harbors, U.S. investors will have access to information about their investments in a more timely and efficient manner. The safe harbors adopted today will facilitate U.S. press access to the offshore press activities, and promote efficiency, competition and capital formation by removing information barriers that may inadvertently harm U.S. investors and otherwise facilitating foreign issuer access to U.S. markets.

V. Cost-Benefit Analysis

The new rule and amendments will not impose any significant new burdens on issuers. No new registration, reporting or filing burdens will be imposed on issuers and selling security holders as a result of the safe harbors. The purpose of the safe harbors is to increase the access of U.S. journalists to the offshore press activities of issuers and selling security holders and, in the case of tender offers, bidders for foreign private issuers and the target company itself. Currently, U.S. journalists are excluded from the offshore press activities of foreign issuers. Instead of protecting U.S. investors, this practice may disadvantage U.S. investors because their access to information is delayed. The new rule and amendments will eliminate this unintended consequence of the Securities Act's regulation of offering publicity.

Although some of the Written Materials Requirements under either safe harbor marginally may increase burdens for those wishing to rely on the safe harbors, these requirements are intended to ensure that activities covered by the safe harbors are not actually offerings of securities or tender offers in the United States. Because the safe harbors should eliminate barriers to press access, the overall result of the safe harbors is to reduce the burdens and costs currently associated with limited and uneven press access. Moreover, the burdens imposed by the Written Materials Requirements are negligible. Based on an informal survey taken by Commission staff of attorneys in private practice whose clients could be expected to rely on these safe harbors, the Commission has estimated that the maximum compliance costs of these legending requirements is $500 in printing costs for each instance that the requirements are triggered.

Under the Securities Act safe harbor, the Written Materials Requirements are intended to help ensure that press-related materials distributed under the safe harbor will not result in an offering of securities to U.S. investors without the protection of the securities laws. The written materials must include a legend explicitly stating that the materials are not an offer of securities in the United States, and that no money or other consideration is being solicited through the materials. The issuer or selling security holder also must state if it intends to register any part of the offering in the United States. In addition to these legending requirements, issuers and selling security holders may not include a purchase order or coupon with the written materials.

Although some commenters contended that these requirements are unnecessary and burdensome, the Commission has determined that these requirements are necessary to safeguard the safe harbor from potential abuse. The burdens imposed are minimal, and enable the Commission to adopt an objective approach that should reduce needless barriers to U.S. press participation in offshore press activities with minimal burden.

The Tender Offer safe harbor contains similar Written Materials Requirements. Bidders for the securities of foreign private issuers and the foreign target companies must comply with these requirements when they release written press-related materials under this safe harbor. The materials must include a legend stating that the materials should not be construed as extending a tender offer in the United States, and that no money or other consideration is being solicited through the materials. If the bidder intends to extend the tender offer in the United States in the future, the written materials must include a statement to that effect. In addition, no coupons or means of tendering securities must be included with the materials.

The requirements under both safe harbors are intended to protect U.S. investors from potential use of the safe harbors as a means of circumventing the protections provided by the federal securities laws. The Commission does not consider these requirements to be unduly burdensome, especially in light of the important investor protections they provide and the benefits provided by the new safe harbors. Moreover, each issuer can engage in its own cost-benefit analysis to determine whether the burdens imposed by the legending and coupon conditions preclude reliance on the safe harbors.

VI. Final Regulatory Flexibility Analysis

This Final Regulatory Flexibility Analysis (''FRFA'') has been prepared in accordance with 5 U.S.C. 604 regarding the new rule and amendments. The rule and amendments are intended to provide companies with greater certainty in determining when journalists, both foreign and domestic, may have access to offshore press conferences, meetings with company representatives conducted offshore, or press materials released offshore without violating the U.S. federal securities laws.

The rule and amendments should eliminate an unintended and potentially harmful consequence of the Securities Act's regulation of offering publicity. Currently, these regulations have been interpreted to deny U.S. journalists access to the offshore press activities of foreign issuers. This practice may harm U.S. investors because they eventually receive the same information, but on a delayed basis. The rule and amendments should remedy this unintended and harmful consequence.

The new rule and amendments will not impose any reporting, recordkeeping or other compliance burdens other than the Written Materials Requirements, which only apply to those issuers that choose to rely on the safe harbors. Although the Written Materials Requirements will impose certain legending requirements on written materials released offshore for those wishing to rely on the safe harbors, the Commission does not consider these requirements to be unduly burdensome on small businesses. A small issuer will make its own determination of whether the requirements would impose too much of a burden to make reliance on

the safe harbors useful to it. As a result, the Commission does not consider the rule and amendments unduly burdensome on small businesses.

The term ''small business,'' as used in reference to an issuer for purposes of the Regulatory Flexibility Act, is defined by Rule 157[48] under the Securities Act as an issuer that had total assets of $5 million or less on the last day of its most recent fiscal year, and is engaged or proposing to engage in small business financing. An issuer is considered to be engaged in small business financing if it is conducting or proposes to conduct an offering of securities that does not exceed the dollar limitation prescribed by Section 3(b) of the Securities Act. When used in reference to an issuer other than an investment company, the term also is defined in Rule 0–10[49] of the Exchange Act as an issuer that had total assets of $5 million or less on the last day of its most recent fiscal year.

The Commission is aware of approximately 1100 Exchange Act reporting companies that currently satisfy the definition of ''small business'' under Rule 0–10. Because the rule and amendments affect multinational offerings by foreign issuers in which there would be press interest, it is likely that most of these issuers would not satisfy the definition of ''small business.''

The Commission has considered different alternatives to the rule and amendments. However, alternatives for providing different means of compliance for small entities or for exempting small entities from the rule and amendments would be inconsistent with the Commission's statutory mandate of investor protection. The new rule and amendments are intended to facilitate U.S. press access to offshore press activities of all issuers, regardless of size, such that further distinctions between companies based on size would not be appropriate.

The Commission requested comment with respect to the Initial Regulatory Flexibility Analysis (''IRFA'') prepared in connection with the Proposing Release, but did not receive any comments that specifically addressed the IRFA.

VII. Statutory Basis for the Amendments

The amendments to the Securities Act rules are being adopted pursuant to Sections 3, 4, 5 and 19 of the Securities Act as amended, and as required by Pub. L. No. 104–290, § 109, 110 Stat. 3416 (1996). The amendment to the Exchange Act rule is being adopted pursuant to Sections 14(d), 14(e) and 23(a) of the Exchange Act.

List of Subjects in 17 CFR Parts 230 and 240

Reporting and recordkeeping requirements, Securities.

Text of the Amendments

In accordance with the foregoing, Title 17, Chapter II of the Code of Federal Regulations is amended as follows:

PART 230—GENERAL RULES AND REGULATIONS, SECURITIES ACT OF 1933

The authority citation for Part 230 continues to read in part as follows:

Authority: 15 U.S.C. 77b, 77f, 77g, 77h, 77j, 77s, 77sss, 78c, 78d, 78*l*, 78m, 78n, 78o, 78w, 78*ll*(d), 79t, 80a–8, 80a–29, 80a–30, and 80a–37, unless otherwise noted.

* * * * *

§ 230.135d [Added]

2. Section 230.135d is added and reserved.

3. By adding § 230.135e to read as follows:

§ 230.135e Offshore press conferences, meetings with issuer representatives conducted offshore, and press-related materials released offshore.

(a) For the purposes only of Section 5 of the Act [15 U.S.C. 77e], an issuer that is a foreign private issuer (as defined in § 230.405) or a foreign government issuer, a selling security holder of the securities of such issuers, or their representatives will not be deemed to offer any security for sale by virtue of providing any journalist with access to its press conferences held outside of the United States, to meetings with issuer or selling security holder representatives conducted outside of the United States, or to written press-related materials released outside the United States, at or in which a present or proposed offering of securities is discussed, if:

(1) The present or proposed offering is not being, or to be, conducted solely in the United States;

Note to Paragraph (a)(1): An offering will be considered not to be made solely in the United States under this paragraph (a)(1) only if there is an intent to make a bona fide offering offshore.

(2) Access is provided to both U.S. and foreign journalists; and

(3) Any written press-related materials pertaining to transactions in which any of the securities will be or are being offered in the United States satisfy the requirements of paragraph (b) of this section.

(b) Any written press-related materials specified in paragraph (a)(3) of this section must:

(1) State that the written press-related materials are not an offer of securities for sale in the United States, that securities may not be offered or sold in the United States absent registration or an exemption from registration, that any public offering of securities to be made in the United States will be made by means of a prospectus that may be obtained from the issuer or the selling security holder and that will contain detailed information about the company and management, as well as financial statements;

(2) If the issuer or selling security holder intends to register any part of the present or proposed offering in the United States, include a statement regarding this intention; and

(3) Not include any purchase order, or coupon that could be returned indicating interest in the offering, as part of, or attached to, the written press-related materials.

(c) For the purposes of this section, ''United States'' means the United States of America, its territories and possessions, any State of the United States, and the District of Columbia.

§ 230.502 [Amended]

4. By amending § 230.502 to remove the period at the end of paragraph (c)(2) and to add the following: ''; *Provided further,* that, if the requirements of § 230.135e are satisfied, providing any journalist with access to press conferences held outside of the United States, to meetings with issuer or selling security holder representatives conducted outside of the United States, or to written press-related materials released outside the United States, at or in which a present or proposed offering of securities is discussed, will not be deemed to constitute general solicitation or general advertising for purposes of this section.''

Preliminary Note 7 [Amended]

5. By amending Preliminary Note 7 following the undesignated heading ''Regulation S'' and before § 230.901 to add the following after the first sentence: ''Where applicable, issuers and bidders may also look to § 230.135e and § 240.14d–1(c) of this chapter.''

6. By amending § 230.902 to add paragraph (b)(8) to read as follows:

§ 230.902 Definitions.

* * * * *

(b) *Directed Selling Efforts.* * * *

(8) Notwithstanding paragraph (b)(1) of this section, providing any journalist

[48] 17 CFR 230.157.

[49] 17 CFR 240.0–10.

with access to press conferences held outside of the United States, to meetings with issuer or selling security holder representatives conducted outside of the United States, or to written press-related materials released outside the United States, at or in which a present or proposed offering of securities is discussed, will not be deemed ''directed selling efforts'' if the requirements of § 230.135e are satisfied.

* * * * *

PART 240—GENERAL RULES AND REGULATIONS, SECURITIES EXCHANGE ACT OF 1934

7. The authority citation for part 240 continues to read in part as follows:

Authority: 15 U.S.C. 77c, 77d, 77g, 77j, 77s, 77z–2, 77eee, 77ggg, 77nnn, 77sss, 77ttt, 78c, 78d, 78f, 78i, 78j, 78k, 78k–1, 78*l*, 78m, 78n, 78o, 78p, 78q, 78s, 78u–5, 78w, 78x, 78*ll*(d), 79q, 79t, 80a–20, 80a–23, 80a–29, 80a–37, 80b–3, 80b–4 and 80b–11, unless otherwise noted.

* * * * *

8. By amending § 240.14d–1 by redesignating paragraphs (c) and (d) as paragraphs (e) and (f), and adding paragraphs (c) and (d) to read as follows:

§ 240.14d–1 Scope of and definitions applicable to regulations 14D and 14E.

* * * * *

(c) Notwithstanding paragraph (a) of this section, the requirements imposed by sections 14(d)(1) through 14(d)(7) of the Act [15 U.S.C. 78n(d)(1) through 78n(d)(7)], Regulation 14D promulgated thereunder (§§ 240.14d–1 through 240.14d–10), and §§ 240.14e–1 and 240.14e–2 shall not apply by virtue of the fact that a bidder for the securities of a foreign private issuer, as defined in § 240.3b–4, the subject company of such a tender offer, their representatives, or any other person specified in § 240.14d–9(d), provides any journalist with access to its press conferences held outside of the United States, to meetings with its representatives conducted outside of the United States, or to written press-related materials released outside the United States, at or in which a present or proposed tender offer is discussed, if:

(1) Access is provided to both U.S. and foreign journalists; and

(2) With respect to any written press-related materials released by the bidder or its representatives that discuss a present or proposed tender offer for equity securities registered under Section 12 of the Act [15 U.S.C. 78*l*], the written press-related materials must state that these written press-related materials are not an extension of a tender offer in the United States for a class of equity securities of the subject company. If the bidder intends to extend the tender offer in the United States at some future time, a statement regarding this intention, and that the procedural and filing requirements of the Williams Act will be satisfied at that time, also must be included in these written press-related materials. No means to tender securities, or coupons that could be returned to indicate interest in the tender offer, may be provided as part of, or attached to, these written press-related materials.

(d) For the purpose of § 240.14d–1(c), a bidder may presume that a target company qualifies as a foreign private issuer if the target company is a foreign issuer and files registration statements or reports on the disclosure forms specifically designated for foreign private issuers, claims the exemption from registration under the Act pursuant to § 240.12g3–2(b), or is not reporting in the United States.

* * * * *

Dated: October 10, 1997.

By the Commission.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 97–27523 Filed 10–16–97; 8:45 am]

BILLING CODE 8010–01–P

DEPARTMENT OF LABOR

Employment Standards Administration

20 CFR Part 702

RIN 1215–AB17

Longshore Act Civil Money Penalties Adjustment

AGENCY: Office of Workers' Compensation Program, Employment Standards Administration, Labor.

ACTION: Final rule.

SUMMARY: On July 2, 1997, the Department of Labor published a proposal to amend various provisions of the regulations implementing the Longshore and Harbor Workers' Compensation Act (LHWCA). More specifically, the amendments, which are now being published in final with only minor word changes in §§ 702.204 and 702.236, will increase the maximum civil penalties that may be assessed under the LHWCA as required by the Federal Civil Penalties Inflation Adjustment Act of 1990 (FCPIAA), as amended by the Debt Collection Improvement Act of 1996 (DCIA).

EFFECTIVE DATE: The rule is effective on November 17, 1997.

FOR FURTHER INFORMATION CONTACT: Joseph F. Olimpio, Director for Longshore and Harbor Workers' Compensation, Employment Standards Administration, Room C–4315, Frances Perkins Building, 200 Constitution Avenue, NW., Washington, DC 20210; Telephone (202) 219–8721.

SUPPLEMENTARY INFORMATION: The LHWCA authorizes the assessment of a civil money penalty in three situations: (1) Where an employer fails to file a report within sixteen days of the final payment of compensation, it shall be assessed a $100.00 civil penalty (LHWCA, section 14(g)); (2) where an employer, insurance carrier, or self-insured employer knowingly and willfully fails to file any report required by section 30, or knowingly or willfully makes a false statement or misrepresentation in any required report, the employer, insurance carrier, or self-insured employer shall be assessed a civil penalty not to exceed $10,000.00 (LHWCA, section 30(e)); and (3) where an employer is found to have discriminated against an employee because the employee had claimed or attempted to claim compensation, or has testified or is about to testify in proceedings under the LHWCA, the employer shall be liable for a civil penalty of not less than $1,000.00 or more than $5,000.00 (LHWCA, section 49). The DCIA, amending the FCPIAA, requires each agency to issue regulations adjusting the amount of civil money penalties they may levy. The DCIA requires that the civil money penalties be adjusted by a cost-of-living increase equal to the percentage, if any, by which the Department of Labor's Consumer Price Index for all-urban customers (CPI) for June of the calendar year preceding the adjustment exceeds the June CPI for the calendar year in which the civil penalty amount was last set or adjusted. Due to inflation since the LHWCA civil money penalties were last set or adjusted, the increase will, in every case, be the maximum 10% initially permitted under the DCIA. The adjusted civil penalties will apply only to violations occurring after the regulations become effective.

The Department did not receive any comments concerning the substance of its proposal. It did, however, receive a letter from the Chief Counsel of the Office of Advocacy at the Small Business Administration requesting clarification on whether the expected increase in the amount to be collected under the revised regulations is $2,500.00 in the aggregate, or $2,500.00 per case. Under the revised rules, the Department expects to collect an additional $2,500.00 for all cases in

which civil money penalties are assessed. This estimate is based on an analysis of the penalties collected in 1995 and 1996. During that period the total civil penalties collected for all cases was $50,000.00, or an average of $25,000.00 for each year. Each year penalties were collected from an average of 206 cases, so that the average penalty in each case was $121.36. Thus, assuming the maximum 10 percent increase is collected in each case under the final rule, the average increase for each individual case is estimated to be $12.14.

Executive Order 12866

The Department has determined that this regulatory action is not a ''significant'' rule within the meaning of Executive Order 12866, because it is not likely to result in: (1) An annual effect on the economy of $100 million or more, or an adverse and material effect on a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities; (2) the creation of a serious inconsistency or interference with an action taken or planned by another agency; (3) a material alteration in the budgetary impacts of entitlement, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) the raising of novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in Executive Order 12866.

Regulatory Flexibility Act

The Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*, requires each agency to perform an initial regulatory flexibility analysis for all proposed rules unless the head of the agency certifies that the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities. Small entities include small businesses, organizations, and governmental jurisdictions. This rule does no more than mechanically increase certain statutory civil money penalties to account for inflation, pursuant to specific directions set forth in the FCPIAA, as amended. The statute specifies the procedure for calculating the adjusted civil money penalties and does not allow the Department to vary the calculation to minimize the effect on small entities. Moreover, as noted above, the total additional amount collected from all projected cases will not exceed $2,500.00. Therefore, the Assistant Secretary hereby certifies that the rule will not have a significant impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act.

Unfunded Mandates Reform Act

For purposes of the Unfunded Mandates Reform Act of 1985, as well as E.O. 12875, this rules does not include any federal mandate that may result in increased expenditures by State, local or tribal government, or increased expenditures by the private sector of more than $100 million.

Paperwork Reduction Act

The rule does not contain any collection of information requirements.

Submission to Congress and the General Accounting Office

In accordance with the Small Business Regulatory Enforcement Act of 1996, the Department will submit to each House of the Congress and to the Comptroller General a report regarding the issuance of today's final rule prior to the effective date set forth at the outset of this notice. The report will note that this rule does not constitute a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 20 CFR Part 702

Administrative practice and procedure, Claims, Insurance, Longshoremen, Vocational rehabilitation, and Workers' Compensation.

For the reasons set forth in the preamble, part 702 of chapter VI of title 20, Code of Federal Regulations, is amended as follows:

PART 702—ADMINISTRATION AND PROCEDURE

1. The authority citation for part 702 is revised to read as follows:

Authority: 5 U.S.C. 301, 8171 *et seq.*, Reorganization Plan No. 6 of 1950, 15 FR 3174, 3 CFR 1949–1953, Comp., p. 1004, 64 Stat. 1263; 28 U.S.C. 2461, 33 U.S.C. 930, 36 D.C. Code 501 *et seq.*, 42 U.S.C. 1651 *et seq.*, 43 U.S.C. 1331; Secretary's Order 5–96, 62 FR 107.

2. Section 702.204 is revised to read as follows:

§ 702.204 Employer's report; penalty for failure to furnish and or falsifying.

Any employer, insurance carrier, or self-insured employer who knowingly and willfully fails or refuses to send any report required by § 702.201, or who knowingly or willfully makes a false statement or misrepresentation in any report, shall be subject to a civil penalty not to exceed $10,000.00 for each such failure, refusal, false statement, or misrepresentation. *Provided, however,* that for any violations occurring on or after November 17, 1997 the maximum civil penalty may not exceed $11,000.00. The district director has the authority and responsibility for assessing a civil penalty under this section.

3. Section 702.236 is revised to read as follows:

§ 702.236 Penalty for failure to report termination of payments.

Any employer failing to notify the district director that the final payment of compensation has been made as required by § 702.235 shall be assessed a civil penalty in the amount of $100.00. *Provided, however,* that for any violation occurring on or after November 17, 1997 the civil penalty will be $110.00. The district director has the authority and responsibility for assessing a civil penalty under this section.

4. Paragraph (a) of § 702.271 is revised to read as follows:

§ 702.271 Discrimination against employees who bring proceedings, prohibition and penalty.

(a)(1) No employer or its duly authorized agent may discharge or in any manner discriminate against an employee as to his/her employment because that employee: (i) Has claimed or attempted to claim compensation under this Act; or (ii) has testified or is about to testify in a proceeding under this Act. To discharge or refuse to employ a person who has been adjudicated to have filed a fraudulent claim for compensation or otherwise made a false statement or misrepresentation under section 31(a)(1) of the Act, 33 U.S.C. 931(a)(1), is not a violation of this section.

(2) Any employer who violates this section shall be liable to a penalty of not less that $1,000.00 or more than $5,000.00 to be paid (by the employer alone, and not by a carrier) to the district director for deposit in the special fund described in section 44 of the Act, 33 U.S.C. 944; and shall restore the employee to his or her employment along with all wages lost due to the discrimination unless the employee has ceased to be qualified to perform the duties of employment. *Provided however,* that for any violation occurring on or after November 17, 1997 the employer shall be liable to a penalty of not less than $1,100.00 or more than $5,500.00.

* * * * *

Signed at Washington, D.C., this 14th day of October 1997.

Bernard E. Anderson,

Assistant Secretary for Employment Standards.

Shelby Hallmark,

Acting Director, Office of Workers' Compensation Programs.

[FR Doc. 97–27593 Filed 10–16–97; 8:45 am]

BILLING CODE 4510–27–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 177

[Docket No. 93F–0111]

Indirect Food Additives: Polymers

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of Nylon 6/66 copolymers as components of nonfood-contact layers of multilayer food packaging used at temperatures that do not exceed 212 °F. This action is in response to a petition filed by Allied-Signal, Inc.

DATES: The regulation is effective October 17, 1997; written objections and requests for a hearing by November 17, 1997.

ADDRESS: Submit written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Vir D. Anand, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3081.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of May 3, 1993 (58 FR 26325), FDA announced that a food additive petition (FAP 3B4369) had been filed by Allied-Signal, Inc., c/o 1100 G St. NW., Washington, DC 20001 (presently c/o Keller and Heckman, 1001 G St. NW., suite 500 West, Washington, DC 20001). The petition proposed to amend the food additive regulations in § 177.1395 *Laminate structures for use at temperatures between 120 °F and 250 °F* (21 CFR 177.1395) to provide for the safe use of Nylon 6/66 copolymers complying with 21 CFR 177.1500(b), item 4.2, as components of nonfood-contact layers of multilayer food packaging used at temperatures that do not exceed 100 °C (212 °F).

In reviewing the environmental assessment (EA), the agency found that the petitioner's proposed regulation was much broader than the proposed use covered in the EA. Whereas the analysis in the EA considered only the use of Nylon 6/66 copolymers in laminate films, the petitioner proposed the use of these copolymers in laminate structures, which includes the use in laminate films. In a subsequent communication with the agency, the petitioner agreed that the proposed regulation should be narrowed to state specifically that the intended use of Nylon 6/66 copolymers is in laminate films. Therefore, this regulation limits the use of these copolymers to laminate films, which is consistent with the proposed use covered in the EA.

FDA has evaluated data in the petition and other relevant material. The agency concludes that the proposed use of the additive is safe, that the additive will have the intended technical effect, and therefore, that the regulations in § 177.1395 should be amended as set forth below.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in § 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

Any person who will be adversely affected by this regulation may at any time on or before November 17, 1997, file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 177

Food additives, Food packaging.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 177 is amended as follows:

PART 177—INDIRECT FOOD ADDITIVES: POLYMERS

1. The authority citation for 21 CFR part 177 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348, 379e.

2. Section 177.1395 is amended in the table in paragraph (b)(4) by revising the entry for ''Nylon 6/66 resins complying with § 177.1500(b), item 4.2 * * *'' to read as follows:

§ 177.1395 Laminate structures for use at temperatures between 120 °F and 250 °F.

* * * * *

(b) * * *

(4) * * *

Substances	Limitations
* * *	* * * *
Nylon 6/66 resins complying with § 177.1500(b), item 4.2 of this chapter (CAS Reg. 24993–04–2).	For use only with: 1. Nonalcoholic foods at temperatures not to exceed 82.2 °C (180 °F). Laminate structures with authorized food-contact materials yield no more than 0.15 milligram of *epsilon*-caprolactam per square inch when extracted with water at 82.2 °C (180 °F) for 5 hours. 2. Nonalcoholic foods at temperatures not to exceed 100 °C (212 °F). Laminate films with authorized food-contact materials yield no more than 0.15 milligram of *epsilon*-caprolactam per square inch when extracted with water at 100 °C (212 °F) for 5 hours.
* * *	* * * *

Dated: September 30, 1997.

Janice F. Oliver,

Deputy Director for Systems and Support, Center for Food Safety and Applied Nutrition.

[FR Doc. 97–27527 Filed 10–16–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1309

[DEA Number—169N]

Comprehensive Methamphetamine Control Act of 1996; Registration Fees

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Notice of fee wavier.

SUMMARY: DEA is waiving a portion of the registration fee for non-retail distributors of pseudoephedrine, phenylpropanolamine, and combination ephedrine drug products. Under the Comprehensive Methamphetamine Control Act of 1996 (MCA), wholesale distributors of these drug products are subject to the existing List I chemical registration and fee requirements. However, because the drug products are distributed in substantially different channels than other List I chemicals, the existing pre-registration investigation procedures, which were established primarily with respect to the handlers of chemicals, as opposed to drug products, are not necessarily applicable to the new type of applicant. DEA will be reviewing the pre-registration investigation procedures to determine what changes will be necessary to account for the different manner of distribution of the drug products. Recognizing that changes are likely to be made in the pre-registration process, thus causing changes to the fees assessed, DEA is waiving a portion of the fee at this time, rather than requiring that new applicants pay a fee that would not be consistent with the resources actually expended in the issuance of the registration.

EFFECTIVE DATE: October 17, 1997.

FOR FURTHER INFORMATION CONTACT: G. Thomas Gitchel, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, Washington, D.C. 20537, Telephone (202) 307–7297.

SUPPLEMENTARY INFORMATION: The MCA's removal of the exemption for pseudoephedrine, phenylpropanolamine, and combination ephedrine drug products (regulated drug products) opens up to chemical registration and regulation a new and different segment of industry from that previously subject to the chemical controls. Prior to the MCA the group subject to chemical registration consisted primarily of specialty chemical handlers distributing products of limited consumer end-use to a largely industrial customer base. By contrast, the principal group subject to registration under the MCA consists of general merchandisers distributing a wide variety of consumer products to retail outlets for sale to the public. Often, one company will operate several distribution centers to serve wholly owned or independent retail outlets. In response to applications submitted by this new group, DEA is re-examining the pre-registration investigation process for issuing registrations. This process will affect the registration application fees.

The procedures for issuing a chemical registration and the associated application fee were developed in 1994 as part of the implementation of the Domestic Chemical Diversion Control Act of 1993 (DCDCA). (For specific details regarding the procedures and fees, see DEA's notice of proposed rulemaking (NPRM) regarding Implementation of the Domestic Chemical Diversion Control Act of 1993 (Pub. L. 103–200) which was published in the **Federal Register** on October 13, 1994 (59 FR 51887)). The procedures were developed based on the type of applicants expected under the DCDCA, e.g., specialty chemical handlers dealing with products of limited consumer end-use. These applicants dealt almost exclusively in chemicals and often distributed from contract operated warehouses/storage depots. Pursuant to the requirements of the Office of Management and Budget (OMB) Circular A–25, the costs and resources required to conduct the pre-registration investigation and issue the registration were assessed to the applicants as the application fee.

The group subject to registration under the MCA is significantly different, consisting principally of general merchandisers distributing hundreds or thousands of different consumer products, often from a large number of applicant-owned warehouse/distribution centers, to retail outlets for sale to the public. The volume of regulated drug products handled is often only a very small portion of the total volume of products distributed by the location. For these applicants,the pre-registration procedures developed for chemical handlers are not entirely suitable. DEA has, therefore, initiated a review of the pre-registration procedures to determine what changes will be necessary to make the process consistent with the different activities of this group of applicants. This review will affect the costs and resources associated with the issuance of registrations to these applicants and, thus, the fee to be charged. DEA will publish notice, with opportunity for comment, in the **Federal Register** regarding any proposed change to the procedures and consequent changes to the fees.

The MCA removed the exemption from regulation for combination ephedrine drug products effective

October 3, 1996, and will remove the exemption from regulation for pseudoephedrine and phenylpropanolamine drug products effective October 3, 1997, making persons who distribute the respective products subject to the registration requirement on those dates. Determination of the appropriate procedures and amendment of the regulations to set the new fees will extend well beyond those deadlines for registration. Therefore, DEA is waiving a portion of the application fee for new registration. It would be inconsistent with the principles of OMB Circular A–25 to charge a fee for a specific service, e.g., completing the processing of the application and the pre-registration investigation, knowing that the costs and resources to be expended in providing that service will change. Persons who have already applied for registration to distribute regulated drug products and paid the existing fee will be refunded the amount of fee that is being waived.

The Acting Deputy Administrator of DEA is, therefore, waiving that portion of the fee for registration as a non-retail distributor of regulated drug products associated with the 12 hours of investigator time allocated for the on-site visit and travel time, which, at $39.92 per hour, amounts to $479.00 (See 59 FR 51892). The remaining administrative costs and time allotted for background checks and reports will continue. Thus the fee for an initial application for registration as a non-retail distributor of regulated drug products is $116.00. That fee will remain in effect until the review of the registration procedures has been completed and a determination has been made regarding how the processing of such applications and the pre-registration investigation will be carried out. At that time, a notice will be published in the **Federal Register** regarding the procedures to be followed and fee that will be required for future applications.

This waiver applies only to applicants for registration as non-retail distributors of regulated drug products. All other applicants remain subject to the full fees, as set forth in Title 21, Code of Federal Regulations, Section 1309.11. As noted earlier, persons who have already submitted an application for registration as a non-retail distributor of regulated drug products and paid the full fee will be provided with a $479.00 refund.

Dated: October 8, 1997.

James S. Milford,

Acting Deputy Administrator.

[FR Doc. 97–27452 Filed 10–16–97; 8:45 am]

BILLING CODE 4410–09–M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Parts 1309 and 1310

[DEA Number 168I]

RIN 1117–AA46

Temporary Exemption From Chemical Registration for Distributors of Pseudoephedrine and Phenylpropanolamine Products

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Interim Rule with request for comments.

SUMMARY: DEA is amending its regulations to provide a temporary exemption from registration for persons who distribute pseudoephedrine and phenylpropanolamine drug products. The Comprehensive Methamphetamine Control Act of 1996 (MCA) amends the Controlled Substances Act of 1970 (CSA) to require that, effective October 3, 1997, persons who distribute these drug products shall be subject to the chemical registration requirement. To avoid interruption in the legitimate distribution of the drug products pending promulgation of final regulations and issuance of registrations, DEA is amending its regulations to provide certain temporary exemptions from the registration requirement.

DATES: October 17, 1997. Persons required to register to handle pseudoephedrine or phenylpropanolamine must submit an application on or before December 3, 1997, in order to continue their activities pending final action by DEA on their application. Written comments or objections must be submitted on or before December 16, 1997.

ADDRESSES: Comments and objections should be submitted in quintuplicate to the Deputy Administrator, Drug Enforcement Administration, Washington, DC 20537, Attention: DEA Federal Register Representative/CCR.

FOR FURTHER INFORMATION CONTACT: G. Thomas Gitchel, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, Telephone (202) 307–7297.

SUPPLEMENTARY INFORMATION: The Comprehensive Methamphetamine Control Act of 1996 (MCA) requires that, effective October 3, 1997, pseudoephedrine and phenylpropanolamine drug products (regulated drug products) will become subject to regulation as List I chemicals. Under this new requirement, any person who wishes to distribute, import, or export these products must first obtain a DEA chemical registration. Because full implementation of this provision and issuance of the registrations will not be possible prior to the October 3, 1997 deadline, DEA is establishing temporary exemptions from the registration requirement for persons handling regulated drug products to allow for continuation of legitimate commerce in the products. In addition, the existing exemptions from chemical registration for persons registered with DEA to handle controlled substances, which is contained in 21 CFR 1309.25, and for distributors of prescription drug products, which is contained in 21 CFR 1309.28, will also apply to the regulated drug products.

The first exemption applies to retail distributors of regulated drug products. A single transaction limit of 24 grams has been established by the MCA for retail distributions of regulated drug products. Consistent with previous proposals regarding the regulation of retail distributions of drug products that contain List I chemicals, DEA is temporarily exempting retail distributors from the registration requirement. Under this exemption, retail distributors will not be required to obtain a registration if they engage exclusively in distributions of regulated drug products below the 24-gram limit in a single transaction for legitimate medical use, either directly to walk-in customers or in face-to-face transactions by direct sales. This exemption is set out in 21 CFR 1309.29(b).

The second exemption applies to those persons who are required to obtain a registration. Any such person who submits an application for registration for activities involving regulated drug products on or before December 3, 1997 will be exempt from the registration requirement for their lawful activities with regulated drug products until the Administration has taken final action with respect to that application. This exemption is set out in 21 CFR 1310.09.

DEA recognizes that, unlike the second exemption, which provides a general benefit to all affected persons, the first exemption is limited in its application. Therefore, while the regulatory changes in this notice take

effect upon publication, the notice is open for public comment or objection until December 16, 1997. Further, the exemptions are temporary and may be subject to change, based on the comments or objections received.

The Deputy Assistant Administrator for the Office of Diversion Control hereby certifies that this interim rulemaking will not have a significant economic impact upon a substantial number of entities whose interests must be considered under the Regulatory Flexibility Act, 5 U.S.C. 601 et seq. This interim rulemaking is an administrative action to make the regulations consistent with the law and to avoid interruption of legitimate commerce by granting temporary exemptions from registration pending promulgation, through notice and comment, of the regulations necessary to implement the provisions of the MCA pertaining to regulated drug products. Further, since this is a temporary action which provides affected persons with a means to comply with the law pending promulgation of regulations implementing the MCA, this action is not a significant regulatory action and therefore has not been reviewed by the Office of Management and Budget pursuant to Executive Order 12866.

This action has been analyzed in accordance with the principles and criteria in Executive Order 12612, and it has been determined that this interim rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

List of Subjects

21 CFR Part 1309

Administrative practice and procedure, Drug traffic control, List I and List II chemicals, Security measures.

21 CFR Part 1310

Drug traffic control, List I and List II chemicals, Reporting and recordkeeping requirements.

For the reasons set out above, 21 CFR parts 1309 and 1310 are amended to read as follows:

PART 1309—[AMENDED]

1. The authority citation for part 1309 continues to read as follows:

Authority: 21 U.S.C. 821, 822, 823, 824, 830, 871(b), 875, 877, 958.

2. Section 1309.29 is revised to read as follows:

§ 1309.29 Exemption of retail distributors of regulated drug products.

The requirement of registration is waived for any retail distributor whose activities with respect to List I chemicals are restricted to the distribution of below-threshold quantities of a drug product that contains a List I chemical that is regulated pursuant to § 1300.02(b)(28)(1)(D) of this chapter to an individual for legitimate medical use.

PART 1310—[AMENDED]

1. The authority citation for part 1310 continues to read as follows:

Authority: 21 U.S.C. 802, 830, 871(b).

2. Section 1310.09 is amended by redesignating the existing text as paragraph (a) and adding a new paragraph (b) to read as follows:

§ 1310.09 Temporary exemption from registration.

* * * * *

(b) Each person required by section 302 of the Act (21 U.S.C. 822) to obtain a registration to distribute, import, or export a drug product that contains pseudoephedrine or phenylpropanolamine that is regulated pursuant to § 1300.02(b)(28)(1)(D) of this chapter is temporarily exempted from the registration requirement, provided that the person submits a proper application for registration on or before December 3, 1997. The exemption will remain in effect for each person who has made such application until the Administration has approved or denied that application. This exemption applies only to registration; all other chemical control requirements set forth in parts 1309, 1310, and 1313 of this chapter remain in full force and effect.

Dated: October 8, 1997.

James S. Milford,

Acting Deputy Administrator.

[FR Doc. 97–27453 Filed 10–16–97; 8:45 am]

BILLING CODE 4410–09–M

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 17

RIN 2900–AH72

Informed Consent for Patient Care

AGENCY: Department of Veterans Affairs.

ACTION: Final rule.

SUMMARY: This document amends VA medical regulations concerning informed consent for patient care. It describes the requirements for obtaining and documenting informed consent. It also describes the types of treatments or procedures for which the patient's or surrogate's signature on a VA-authorized form is required and establishes a list and priority of surrogates authorized to act on behalf of patients who lack decision-making capacity. Further, it establishes an internal decision-making process for patients who lack decision-making capacity and who have no authorized surrogate. This is intended to protect patient rights and ensure that the patient (or the patient's surrogate or representative) receives sufficient information to make an informed health-care decision.

DATES: *Effective Date:* November 17, 1997.

FOR FURTHER INFORMATION CONTACT: Ruth-Ann Phelps, Ph.D., Veterans Health Administration, Patient Care Services (11B), 810 Vermont Avenue, NW, Washington, DC 20420, (202) 273–8473.

SUPPLEMENTARY INFORMATION: In a document published in the **Federal Register** on August 7, 1996 (61 FR 41108), we proposed to amend our regulations concerning informed consent for patient care. Interested parties were invited to submit written comments on or before October 7, 1996. We received comments from one commenter, the American Psychiatric Association.

Comments

The commenter suggested that whenever the word ''patient'' appears in the document, the phrase ''or patient surrogate'' should be added. In response, we have added the words ''or surrogate'' wherever appropriate. This is intended to clarify, consistent with the intent of the proposal, that a surrogate may give informed consent on behalf of a patient who lacks decision-making capacity.

With respect to requirements regarding the administration of psychotropic medication to an involuntarily committed patient, the commenter asserted that the prescribing of such medications should be limited to psychiatrists, and further asserted that the multi-disciplinary review committee constituted for purposes of review of the decision to administer or continue the administration of such medications should be required to include a psychiatrist. We do not believe that psychotropic medication should be prescribed only by psychiatrists. We believe that patients are adequately served as long as the prescribing physician is privileged to prescribe such medication. Also, we have added the requirement that the committee must include a psychiatrist or a physician who has

psychopharmacology privileges. We believe this is adequate for the types of determinations that need to be made.

With respect to the revocation of consent (including the revocation of HIV testing consent), the commenter suggested that the regulations should require that documentation immediately be added at the place in the medical records that contained the earlier record of consent. No changes are made based on this comment. We note that the regulations provide that the informed consent process must be appropriately documented in the medical record. This requires documentation for revocations of consent, and we do not believe further instructions in the regulations are necessary (see § 17.32(d)).

The commenter suggested that consents regarding HIV testing (required to be on VA form 10–012) be filed in the patient record. No changes are made based on this comment. This already is required by these regulations (see § 17.32(g)(4)).

The proposal provided that HIV antibody testing must be accomplished by pre-test and post-test counseling. The commenter suggested that the counseling be at least equivalent to guidelines for testing from the Centers for Disease Control and Prevention and other Federal or State agencies which set HIV serologic testing policies. The commenter further suggested that the form and language of such counseling should be appropriate to the patient's or surrogate's educational level as well as cognitive and emotional state. No changes are made based on these comments. VA health-care professionals are provided with guidance commensurate with the guidelines suggested by the commenter. Further, there does not appear to be a need to specifically address the educational level and cognitive and emotional state of the patient or surrogate. This already is covered since the final rule requires that health-care professionals explain consent matters in language understandable to the patient or surrogate (see § 17.32(c)).

Paperwork Reduction Act

The collection of information contained in the notice of the proposed rulemaking was submitted to the Office of Management and Budget (OMB) for review in accordance with the Paperwork Reduction Act (44 U.S.C. 3504(h)). The information collection subject to this rulemaking concerns the disclosure requirements that non-VA physicians contracting to perform services for VA must follow in conducting informed consent procedures. The information provided is designed to ensure that the patients (or in some cases, others) have sufficient information to provide informed consent. Interested parties were invited to submit comments on the collection of information. However, no comments were received. OMB has approved this information collection under control number 2900–0583.

VA is not authorized to impose a penalty on persons for failure to comply with information collection requirements which do not display a current OMB control number, if required.

Executive Order 12866

This final rule has been reviewed by OMB under Executive Order 12866.

Regulatory Flexibility Act

The Secretary hereby certifies that the adoption of this final rule would not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601–612. The adoption of the final rule would affect VA beneficiaries but would not affect small businesses. Therefore, pursuant to 5 U.S.C. 605(b), this rulemaking is exempt from the initial and final regulatory flexibility analyses requirements of §§ 603 and 604.

The Catalog of Federal Domestic Assistance Program numbers are 64.009, 64.010, 64.011.

Lists of Subjects in 38 CFR Part 17

Administrative practice and procedure, Alcohol abuse, Alcoholism, Claims, Day care, Dental health, Drug abuse, Foreign relations, Government contracts, Grant programs-health, Grant programs-veterans, Health care, Health facilities, Health professions, Health records, Homeless, Medical and Dental schools, Medical devices, Medical research, Mental health programs, Nursing home, Philippines, Reporting and recordkeeping requirements, scholarships and fellowships, Travel and transportation expenses, and Veterans.

Approved: September 5, 1997.

Hershel W. Gober,

Acting Secretary of Veterans Affairs.

In consideration of the foregoing, 38 CFR part 17 is amended as set forth below:

PART 17—MEDICAL

1. The authority citation for part 17 continues to read as follows:

Authority: 38 U.S.C. 501, 1721, unless otherwise noted.

2. Section 17.32 is revised to read as follows:

Protection of Patient Rights

§ 17.32 Informed consent.

(a) *Definitions*:

Close Friend. Any person eighteen years or older who has shown care and concern for the patient's welfare, who is familiar with the patient's activities, health, religious beliefs and values, and who has presented a signed written statement for the record that describes that person's relationship to and familiarity with the patient.

Decision-making capacity. The ability to understand and appreciate the nature and consequences of health-care treatment decisions.

Health-Care Agent. An individual named by the patient in a Durable Power of Attorney for Health Care.

Legal Guardian. A person appointed by a court of appropriate jurisdiction to make decisions for an individual who has been judicially determined to be incompetent.

Practitioner. Any physician, dentist, or health-care professional who has been granted specific clinical privileges to perform the treatment or procedure involved. For the purpose of obtaining informed consent for medical treatment, the term practitioner includes medical and dental residents regardless of whether they have been granted clinical privileges.

Signature consent. The patient's or surrogate's signature on a VA-authorized consent form, *e.g.*, a published numbered VA form (OF 522) or comparable form approved by the local VA facility.

Special Guardian. A person appointed by a court of appropriate jurisdiction for the specific purpose of making health-care decisions.

Surrogate. An individual, organization or other body authorized under this section to give informed consent on behalf of a patient who lacks decision-making capacity.

(b) *Policy.* Except as otherwise provided in this section, all patient care furnished under title 38 U.S.C. shall be carried out only with the full and informed consent of the patient or, in appropriate cases, a representative thereof. In order to give informed consent, the patient must have decision-making capacity and be able to communicate decisions concerning health care. If the patient lacks decision-making capacity or has been declared incompetent, consent must be obtained from the patient's surrogate. Practitioners may provide necessary medical care in emergency situations

without the patient's or surrogate's express consent when immediate medical care is necessary to preserve life or prevent serious impairment of the health of the patient or others and the patient is unable to consent and the practitioner determines that the patient has no surrogate or that waiting to obtain consent from the patient's surrogate would increase the hazard to the life or health of the patient or others. In such circumstances consent is implied.

(c) *General requirements for informed consent.* Informed consent is the freely given consent that follows a careful explanation by the practitioner to the patient or the patient's surrogate of the proposed diagnostic or therapeutic procedure or course of treatment. The practitioner, who has primary responsibility for the patient or who will perform the particular procedure or provide the treatment, must explain in language understandable to the patient or surrogate the nature of a proposed procedure or treatment; the expected benefits; reasonably foreseeable associated risks, complications or side effects; reasonable and available alternatives; and anticipated results if nothing is done. The patient or surrogate must be given the opportunity to ask questions, to indicate comprehension of the information provided, and to grant permission freely without coercion. The practitioner must advise the patient or surrogate if the proposed treatment is novel or unorthodox. The patient or surrogate may withhold or revoke his or her consent at any time.

(d) *Documentation of informed consent.* (1) The informed consent process must be appropriately documented in the medical record. In addition, signature consent is required for all diagnostic and therapeutic treatments or procedures that:

(i) Require the use of sedation;

(ii) Require anesthesia or narcotic analgesia;

(iii) Are considered to produce significant discomfort to the patient;

(iv) Have a significant risk of complication or morbidity;

(v) Require injections of any substance into a joint space or body cavity; or

(vi) Involve testing for Human Immunodeficiency Virus (HIV).

(2) The patient's or surrogate's signature on a VA-authorized consent form must be witnessed. The witness' signature only attests to the fact that he or she saw the patient or surrogate and the practitioner sign the form. When the patient's or surrogate's signature is indicated by an ''X'', two adults must witness the act of signing. The signed form must be filed in the patient's medical record. A properly executed OF 522 or other VA-authorized consent form is valid for a period of 30 calendar days. If, however, the treatment plan involves multiple treatments or procedures, it will not be necessary to repeat the informed consent discussion and documentation so long as the course of treatment proceeds as planned, even if treatment extends beyond the 30-day period. If there is a change in the patient's condition that might alter the diagnostic or therapeutic decision, the consent is automatically rescinded.

(3) If it is impractical to consult with the surrogate in person, informed consent may be obtained by mail, facsimile, or telephone. A facsimile copy of a signed consent form is adequate to proceed with treatment. However, the surrogate must agree to submit a signed consent form to the practitioner. If consent is obtained by telephone, the conversation must be audiotaped or witnessed by a second VA employee. The name of the person giving consent and his or her authority to act as surrogate must be adequately identified for the record.

(e) *Surrogate consent.* If the practitioner who has primary responsibility for the patient determines that the patient lacks decision-making capacity and is unlikely to regain it within a reasonable period of time, informed consent must be obtained from the patient's surrogate. Patients who are incapable of giving consent as a matter of law, i.e., persons judicially determined to be incompetent and minors not otherwise able to provide informed consent, will be deemed to lack decision-making capacity for the purposes of this section. If the patient is considered a minor in the state where the VA facility is located and cannot consent to medical treatment, consent must be obtained from the patient's parent or legal guardian. The surrogate generally assumes the same rights and responsibilities as the patient in the informed consent process. The surrogate's decision must be based on his or her knowledge of what the patient would have wanted, *i.e.*, substituted judgment. If the patient's wishes are unknown, the decision must be based on the patient's best interest. The following persons are authorized to consent on behalf of patients who lack decision-making capacity in the following order of priority:

(1) Health-care agent;

(2) Legal guardian or special guardian;

(3) Next-of-kin: a close relative of the patient eighteen years of age or older, in the following priority: spouse, child, parent, sibling, grandparent, or grandchild; or

(4) Close friend.

(f) *Consent for patients without surrogates.* (1) If none of the surrogates listed in paragraph (e) of this section are available, the practitioner may request Regional Counsel assistance to obtain a special guardian for health care or follow the procedures outlined in this paragraph (f).

(2) Facilities may use the following process to make treatment decisions for patients who lack decision-making capacity and have no surrogate. For treatments or procedures that involve minimal risk, the practitioner must verify that no authorized surrogate can be located. The practitioner must attempt to explain the nature and purpose of the proposed treatment to the patient and enter this information in the medical record. For procedures that require signature consent, the practitioner must certify that the patient has no surrogate. The attending physician and the Chief of Service (or his or her designee) must indicate their approval of the treatment decision in writing. Any decision to withhold or withdraw life-sustaining treatment for such patients must be reviewed by a multi-disciplinary committee appointed by the facility Director. The committee functions as the patient's advocate and may not include members of the treatment team. The committee must submit its findings and recommendations in a written report to the Chief of Staff who must note his or her approval of the report in writing. After reviewing the record, the facility Director may concur with the decision to withhold or withdraw life support or request further review by Regional Counsel.

(g) *Special consent situations.* In addition to the other requirements of this section, additional protections are required in the following situations.

(1) No patient will undergo any unusual or extremely hazardous treatment or procedure, *e.g.*, that which might result in irreversible brain damage or sterilization, except as provided in this paragraph (g). Before treatment is initiated, the patient or surrogate must be given adequate opportunity to consult with independent specialists, legal counsel or other interested parties of his or her choosing. The patient's or surrogate's signature on a VA authorized consent form must be witnessed by someone who is not affiliated with the VA health-care facility, *e.g.*, spouse, legal guardian, or patient advocate. If a surrogate makes the treatment decision, a multi-

disciplinary committee, appointed by the facility Director, must review that decision to ensure it is consistent with the patient's wishes or in his or her best interest. The committee functions as the patient's advocate and may not include members of the treatment team. The committee must submit its findings and recommendations in a written report to the facility Director. The Director may authorize treatment consistent with the surrogate's decision or request that a special guardian for health care be appointed to make the treatment decision.

(2) Administration of psychotropic medication to an involuntarily committed patient against his or her will must meet the following requirements. The patient or surrogate must be allowed to consult with independent specialists, legal counsel or other interested parties concerning the treatment with psychotropic medication. Any recommendation to administer or continue medication against the patient's or surrogate's will must be reviewed by a multi-disciplinary committee appointed by the facility Director for this purpose. This committee must include a psychiatrist or a physician who has psychopharmacology privileges. The facility Director must concur with the committee's recommendation to administer psychotropic medications contrary to the patient's or surrogate's wishes. Continued therapy with psychotropic medication must be reviewed every 30 days. The patient (or a representative on the patient's behalf) may appeal the treatment decision to a court of appropriate jurisdiction.

(3) If a proposed course of treatment or procedure involves approved medical research in whole or in part, the patient or representative shall be advised of this. Informed consent shall be obtained specifically for the administration or performance of that aspect of the treatment or procedure that involves research. Such consent shall be in addition to that obtained for the administration or performance of the nonresearch aspect of the treatment or procedure and must meet the requirements for informed consent set forth in 38 CFR Part 16, *Protection of Human Subjects.*

(4) Testing for Human Immunodeficiency Virus (HIV) must be voluntary and must be conducted only with the prior informed and (written) signature consent of the patient or surrogate. Patients who consent to testing for HIV must sign VA form 10–012, ''Consent for HIV Antibody Testing.'' This form must be filed in the patient's medical record. Testing must be accompanied by pre-test and post-test counseling.

(The information collection requirements in this section have been approved by the Office of Management and Budget under control number 2900–0583)

(Authority: 38 U.S.C. 7331, 7332, 7333)

[FR Doc. 97–27565 Filed 10–16–97; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 36

RIN 2900–AI16

Loan Guaranty: Credit Standards

AGENCY: Department of Veterans Affairs.

ACTION: Final rule.

SUMMARY: This document amends the Department of Veterans Affairs (VA) loan guaranty regulations regarding credit standards used by lenders to evaluate the creditworthiness of veteran-borrowers for home loans. VA is committed to regular review and revision of the standards used to determine the creditworthiness of veteran-applicants as issues arise and as the mortgage industry changes. These changes are designed to keep VA in step with the rest of the home mortgage industry, at least to an extent appropriate for a Government benefit-related mortgage program.

DATES: Effective Date: November 17, 1997.

FOR FURTHER INFORMATION CONTACT: Ms. Judith Caden, Assistant Director for Loan Policy (264), Loan Guaranty Service, Veterans Benefits Administration, Department of Veterans Affairs, 810 Vermont Avenue, NW, Washington, DC 20420, (202) 273–7368.

SUPPLEMENTARY INFORMATION: In a document published in the **Federal Register** on May 7, 1997 (62 FR 24874), VA proposed to amend its loan guaranty credit standards, set forth at 38 CFR 36.4337, used by lenders to evaluate the creditworthiness of veteran-borrowers for home loans. Based on the rationale set forth in the proposed rule and this document the proposed changes are adopted, with differences explained below.

Please refer to the May 7, 1997, **Federal Register** for a complete discussion of the proposed amendments. Interested persons were given 60 days to submit comments. The comment period ended July 7, 1997. VA received three comments regarding the proposed changes.

The first commenter, an association which represents mortgage lenders, supported adoption of the proposed rule.

The second commenter, an association representing home builders, suggested that the language of proposed paragraph 36.4337(c)(5)(xii) be changed to accept other forms of tax credits in addition to those for child care as compensating factors. This was intended to cover child care tax credits of a continuing nature. VA agrees that there is no basis for distinguishing child care tax credits from other forms of tax credits of a continuing nature. The final rule at paragraph 36.4337(c)(5)(xii) is changed accordingly.

The third commenter, a lender who actively participates in the VA Guaranteed Home Loan Program, expressed general support for the proposed rule, but raised several concerns. The first concern related to proposed paragraphs 36.4337 (d) and (f), which would allow lenders to ''gross up'' income to account for the impact of tax-free income on the debt-to-income-ratio when underwriting a loan. The commenter observed that the ''grossing-up'' calculations should be kept simple and suggested that it would be helpful if VA could provide an example or formula of how ''grossing up'' calculations are performed. We agree that the ''grossing up'' calculation needs to be simple and understandable and believe that the revised regulations on this point are simple and understandable. Also, we note that the term ''grossing up'' is well understood by the mortgage industry. The mortgage industry has been ''grossing up'' income on conventional loans for many years.

Under paragraph 36.4337(f)(4), the adjustment may be made by using current income tax tables. The lender need only determine what amount of income, when taxed at the proper combination of State and Federal rates, would yield an after-tax income equivalent to the tax-free income the veteran actually receives. The purpose of allowing lenders to ''gross up'' income is to enable the lender to calculate the debt-to-income ratio as if the veteran's tax-free income were ''after-tax'' income. The arithmetic will vary by State, depending on various State and local tax rates. The lender would then use this amount to calculate the veteran's debt-to-income ratio, while using the actual tax-free income to calculate the residual income.

For example, in a State with no income tax, the lender could simply show that, for a veteran in the 15 percent Federal income tax bracket, $1,000 of tax-free income is equivalent

to 85 percent of taxable income. Thus, by dividing $1,000 by .85, it is possible to calculate that the ''grossed up'' income is $1,176.50. In a State with a 5 percent income tax, the ''grossed up'' income would be calculated by combining the State and Federal tax rates, 20 percent. Thus in the same example, $1,000 of tax-free income would be ''grossed up'' by dividing it by .80 and the ''grossed up'' income is $1,250.

Note: This amount is a close estimate if the veteran itemizes deductions, since the State income tax is deductible in calculating federal income tax. No particular form is prescribed for this material (see paragraph 36.4337(f)(4)). It can be on a separate sheet of paper, or simply explained on the loan analysis form, so long as the explanation is one that would be understandable to a VA or other agency loan specialist trained in reviewing loan applications, or can be made understandable with any further information the lender wishes to submit.

The commenter questioned whether the change to VA's residual income guidelines in paragraph 36.4337(e) is a one-time adjustment or whether VA was providing for automatic future annual adjustments. The answer is that this is a one-time increase. Paragraph 36.4337(e) is being changed by increasing the amount of residual income required for family support by 4 percent for all categories. The computation of the Residual Income tables is based upon cost-of-living and expenditure data compiled by the U.S. Bureau of Labor Statistics. These tables have not been increased since 1992. This amendment increases the Residual Income amounts by 4 percent across the board. Any future adjustments will be made by separate regulatory actions.

This commenter also raised an issue regarding the inclusion of all household members in the residual income calculations set forth in paragraph 36.4337(e). More specifically, the commenter questioned whether lenders would be required to verbally confirm that there are no additional non-claimed dependents in the veteran's household. No changes are made based on this comment. Prudent lenders clearly would discuss the information provided by the veteran and a lender would need to ask sufficient questions to ensure the completeness and accuracy of the information provided for a loan.

In its comments, this commenter stated that imposing the same documentation requirements for Reserve and National Guard applicants that are currently required for active military personnel within 12 months of release is somewhat burdensome. Currently, under paragraph 36.4337(f)(2)(ii), active duty military personnel who are within 12 months of release must provide one of the following: (1) Documentation that the servicemember has in fact already reenlisted or extended his/her period of active duty to a date beyond the 12-month period following the projected closing of the loan; (2) Verification of a valid offer of local civilian employment following release from active duty, which includes all data pertinent to sound underwriting procedures such as date employment will begin, earnings, etc.; (3) A statement from the servicemember that he/she intends to reenlist or extend his/her period of active duty to a date beyond the 12 month period following the projected loan closing date, and a statement from the servicemember's commanding officer confirming that the servicemember is eligible to reenlist or extend his/her active duty as indicated and that the commanding officer has no reason to believe that such reenlistment or extension of active duty will not be granted; or (4) Other unusually strong positive underwriting factors, such as a downpayment of at least 10 percent, significant cash reserves, or clear evidence of strong ties to the community coupled with a nonmilitary spouse's income so high that only a minimal income from the active duty servicemember is needed to qualify.

In light of the fact that members of the Selected Reserves are subject to the same downsizing as the regular military, we believe that if the income from service in the Reserves is necessary to qualify it must likewise be subject to the same stability criteria. For this reason, VA does not believe any substantive change to this paragraph of the proposed regulatory amendments is warranted.

Finally, this commenter has requested further clarification regarding the treatment of employment history and the probability of the veteran's continued employment. If a veteran has a short-term employment history or has recently changed to a new career, it very well may not be possible to determine that the veteran's income is stable. The purpose of the change is to remove the burden of trying to follow up with an employer when the employer declines to verify the probability of continued employment. Instead, reliability will be determined based on the duration of the borrower's current employment together with his or her overall documented employment history.

Nonsubstantive changes have been made for purposes of clarification.

Paperwork Reduction Act

Information collection and recordkeeping requirements in 38 CFR 36.4337 have been approved by the Office of Management and Budget (OMB) under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) and have been assigned OMB control number 2900–0521. The information collection subject to this rulemaking concerns the information to be submitted for approval of a VA loan guaranty and contains material which further explains the quality of the information needed for approval.

OMB assigns a control number for each collection of information it approves. VA may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The valid OMB control number assigned to the collection of information in this final rule is displayed at the end of the affected section of the regulations.

Interested persons were invited to submit comments on the collection of information. All comments received are discussed above.

The Secretary hereby certifies that this final rule will not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601–612. Industry norms for other lending programs already require lenders to comply with most of the standards set forth in this final rule. Further, activities concerning loans subject to the VA Loan Guaranty Program do not constitute a significant portion of activities of small businesses. Therefore, pursuant to 5 U.S.C. 605(b), this final rule is exempt from the initial and final regulatory flexibility analysis requirements of §§ 603 and 604.

The Catalog of Federal Domestic Assistance Program numbers are 64.106, 64.114, 64.118 and 64.119.

List of Subjects in 38 CFR Part 36

Condominiums, Handicapped, Housing, Loan programs—housing and community development, Reporting and recordkeeping requirements, Veterans.

Approved: September 5, 1997.

Hershel W. Gober,

Acting Secretary of Veterans Affairs.

For the reasons set out in the preamble, 38 CFR part 36 is amended as set forth below.

PART 36—LOAN GUARANTY

1. The authority citation for part 36 continues to read as follows:

Authority: 38 U.S.C. 501, 3701–3704, 3707, 3710–3714, 3719, 3720, 3729, 3762, unless otherwise noted.

2. In § 36.4337, the section heading; paragraphs (c) through (h), (j) through (l), and (n); and the section authority citation are revised to read as follows:

§ 36.4337 Underwriting standards, processing procedures, lender responsibility, and lender certification.

* * * * *

(c) *Methods.* The two primary underwriting tools that will be used in determining the adequacy of the veteran's present and anticipated income are debt-to-income ratio and residual income analysis. They are described in paragraphs (d) through (f) of this section. Ordinarily, to qualify for a loan, the veteran must meet both standards. Failure to meet one standard, however, will not automatically disqualify a veteran. The following shall apply to cases where a veteran does not meet both standards:

(1) If the debt-to-income ratio is 41 percent or less, and the veteran does not meet the residual income standard, the loan may be approved with justification, by the underwriter's supervisor, as set out in paragraph (c)(4) of this section.

(2) If the debt-to-income ratio is greater than 41 percent (unless it is larger due solely to the existence of tax-free income which should be noted in the loan file), the loan may be approved with justification, by the underwriter's supervisor, as set out in paragraph (c)(4) of this section.

(3) If the ratio is greater than 41 percent and the residual income exceeds the guidelines by at least 20 percent, the second level review and statement of justification are not required.

(4) In any case described by paragraphs (c)(1) and (c)(2) of this section, the lender must fully justify the decision to approve the loan or submit the loan to the Secretary for prior approval in writing. The lender's statement must not be perfunctory, but should address the specific compensating factors, as set forth in paragraph (c)(5) of this section, justifying the approval of the loan. The statement must be signed by the underwriter's supervisor. It must be stressed that the statute requires not only consideration of a veteran's present and anticipated income and expenses, but also that the veteran be a satisfactory credit risk. Therefore, meeting both the debt-to-income ratio and residual income standards does not mean that the loan is automatically approved. It is the lender's responsibility to base the loan approval or disapproval on all the factors present for any individual veteran. The veteran's credit must be evaluated based on the criteria set forth in paragraph (g) of this section as well as a variety of compensating factors that should be evaluated.

(5) The following are examples of acceptable compensating factors to be considered in the course of underwriting a loan:

(i) Excellent long-term credit;

(ii) Conservative use of consumer credit;

(iii) Minimal consumer debt;

(iv) Long-term employment;

(v) Significant liquid assets;

(vi) Downpayment or the existence of equity in refinancing loans;

(vii) Little or no increase in shelter expense;

(viii) Military benefits;

(ix) Satisfactory homeownership experience;

(x) High residual income;

(xi) Low debt-to-income ratio;

(xii) Tax credits of a continuing nature, such as tax credits for child care; and

(xiii) Tax benefits of home ownership.

(6) The list in paragraph (c)(5) of this section is not exhaustive and the items are not in any priority order. Valid compensating factors should represent unusual strengths rather than mere satisfaction of basic program requirements. Compensating factors must be relevant to the marginality or weakness.

(d) *Debt-to-income ratio.* A debt-to-income ratio that compares the veteran's anticipated monthly housing expense and total monthly obligations to his or her stable monthly income will be computed to assist in the assessment of the potential risk of the loan. The ratio will be determined by taking the sum of the monthly Principal, Interest, Taxes and Insurance (PITI) of the loan being applied for, homeowners and other assessments such as special assessments, condominium fees, homeowners association fees, etc., and any long-term obligations divided by the total of gross salary or earnings and other compensation or income. The ratio should be rounded to the nearest two digits; e.g., 35.6 percent would be rounded to 36 percent. The standard is 41 percent or less. If the ratio is greater than 41 percent, the steps cited in paragraphs (c)(1) through (c)(6) of this section apply.

(e) *Residual income guidelines.* The guidelines provided in this paragraph for residual income will be used to determine whether the veteran's monthly residual income will be adequate to meet living expenses after estimated monthly shelter expenses have been paid and other monthly obligations have been met. All members of the household must be included in determining if the residual income is sufficient. They must be counted even if the veteran's spouse is not joining in title or on the note, or if there are any other individuals depending on the veteran for support, such as children from a spouse's prior marriage who are not the veteran's legal dependents. It is appropriate, however, to reduce the number of members of a household to be counted for residual income purposes if there is sufficient verified income not otherwise included in the loan analysis, such as child support being regularly received as discussed in paragraph (e)(4) of this section. In the case of a spouse not to be obligated on the note, verification that he/she has stable and reliable employment as discussed in paragraph (f)(3) of this section would allow not counting the spouse in determining the sufficiency of the residual income. The guidelines for residual income are based on data supplied in the Consumer Expenditure Survey (CES) published by the Department of Labor's Bureau of Labor Statistics. Regional minimum incomes have been developed for loan amounts up to $79,999 and for loan amounts of $80,000 and above. It is recognized that the purchase price of the property may affect family expenditure levels in individual cases. This factor may be given consideration in the final determination in individual loan analyses. For example, a family purchasing in a higher-priced neighborhood may feel a need to incur higher-than-average expenses to support a lifestyle comparable to that in their environment, whereas a substantially lower-priced home purchase may not compel such expenditures. It should also be clearly understood from this information that no single factor is a final determinant in any applicant's qualification for a VA-guaranteed loan. Once the residual income has been established, other important factors must be examined. One such consideration is the amount being paid currently for rental or housing expenses. If the proposed shelter expense is materially in excess of what is currently being paid, the case may require closer scrutiny. In such cases, consideration should be given to the ability of the borrower and spouse to accumulate liquid assets, such as cash and bonds, and to the amount of debts incurred while paying a lesser amount for shelter. For example, if an application indicates little or no capital reserves and excessive obligations, it may not be

reasonable to conclude that a substantial increase in shelter expenses can be absorbed. Another factor of prime importance is the applicant's manner of meeting obligations. A poor credit history alone is a basis for disapproving a loan, as is an obviously inadequate income. When one or the other is marginal, however, the remaining aspect must be closely examined to assure that the loan applied for will not exceed the applicant's ability or capacity to repay. Therefore, it is important to remember that the figures provided below for residual income are to be used as a guide and should be used in conjunction with the steps outlined in paragraphs (c) through (j) of this section. The residual income guidelines are as follows:

(1) Table of residual incomes by region (for loan amounts of $79,999 and below):

TABLE OF RESIDUAL INCOMES BY REGION

[For loan amounts of $79,999 and below]

Family size*	Northeast	Midwest	South	West
1	390	382	382	425
2	654	641	641	713
3	788	772	772	859
4	888	868	868	967
5	921	902	902	1,004

*For families with more than five members, add $75 for each additional member up to a family of seven. ''Family'' includes all members of the household.

(2) Table of residual incomes by region (for loan amounts of $80,000 and above):

TABLE OF RESIDUAL INCOMES BY REGION

[For loan amounts of $80,000 and above]

Family size*	Northeast	Midwest	South	West
1	450	441	441	491
2	755	738	738	823
3	909	889	889	990
4	1,025	1,003	1,003	1,117
5	1,062	1,039	1,039	1,158

* For families with more than five members, add $80 for each additional member up to a family of seven. ''Family'' includes all members of the household.

(3) *Geographic regions for residual income guidelines:* Northeast—Connecticut, Maine, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island and Vermont; Midwest—Illinois, Indiana, Iowa, Kansas, Michigan, Minnesota, Missouri, Nebraska, North Dakota, Ohio, South Dakota and Wisconsin; South—Alabama, Arkansas, Delaware, District of Columbia, Florida, Georgia, Kentucky, Louisiana, Maryland, Mississippi, North Carolina, Oklahoma, Puerto Rico, South Carolina, Tennessee, Texas, Virginia, West Virginia; West—Alaska, Arizona, California, Colorado, Hawaii, Idaho, Montana, Nevada, New Mexico, Oregon, Utah, Washington and Wyoming.

(4) *Military adjustments.* For loan applications involving an active-duty servicemember or military retiree, the residual income figures will be reduced by a minimum of 5 percent if there is a clear indication that the borrower or spouse will continue to receive the benefits resulting from the use of facilities on a nearby military base. (This reduction applies to tables in paragraph (e) of this section.)

(f) *Stability and reliability of income.* Only stable and reliable income of the veteran and spouse can be considered in determining ability to meet mortgage payments. Income can be considered stable and reliable if it can be concluded that it will continue during the foreseeable future.

(1) *Verification.* Income of the borrower and spouse which is derived from employment and which is considered in determining the family's ability to meet the mortgage payments, payments on debts and other obligations, and other expenses must be verified. If the spouse is employed and will be contractually obligated on the loan, the combined income of both the veteran and spouse is considered when the income of the veteran alone is not sufficient to qualify for the amount of the loan sought. In other than community property states, if the spouse will not be contractually obligated on the loan, Regulation B (12 CFR part 202), promulgated by the Federal Reserve Board pursuant to the Equal Credit Opportunity Act, prohibits any request for, or consideration of, information concerning the spouse (including income, employment, assets, or liabilities), except that if the applicant is relying on alimony, child support, or maintenance payments from a spouse or former spouse as a basis for repayment of the loan, information concerning such spouse or former spouse may be requested and considered (see paragraph (f)(4) of this section). In community property states, information concerning a spouse may be requested and considered in the same manner as that for the applicant. The standards applied to income of the veteran are also applicable to that of the spouse. There can be no discounting of income on account of sex, marital status, or any other basis prohibited by the Equal Credit Opportunity Act. Income claimed by an applicant that is not or cannot be verified cannot be considered when analyzing the loan. If the veteran or spouse has been employed by a present employer for less than 2 years, a 2-year history covering prior employment, schooling, or other training must be secured. Any periods of unemployment must be explained. Employment verifications and pay stubs must be no more than 120 days (180 days for new construction) old to be considered valid. For loans closed automatically, this requirement will be considered satisfied if the date of the employment verification is within 120 days (180 days for new construction) of the date the note is signed. For prior approval loans, this requirement will be considered satisfied if the verification of employment is dated within 120 days of the date the application is received by VA.

(2) *Active-duty, Reserve, or National Guard applicants.* (i) In the case of an active-duty applicant, a military Leave & Earnings Statement is required and will be used instead of an employment verification. The statement must be no more than 120 days old (180 days for new construction) and must be the original or a lender-certified copy of the original. For loans closed automatically, this requirement is satisfied if the date of the Leave & Earnings Statement is within 120 days (180 days for new construction) of the date the note is signed. For prior approval loans, this requirement will be considered satisfied if the verification of employment is dated within 120 days of the date the application is received by VA.

(ii) For servicemembers within 12 months of release from active duty, or members of the Reserves or National Guard within 12 months of release, one of the following is also required:

(A) Documentation that the servicemember has in fact already reenlisted or extended his/her period of active duty or Reserve or National Guard service to a date beyond the 12-month period following the projected closing of the loan.

(B) Verification of a valid offer of local civilian employment following release from active duty. All data pertinent to sound underwriting procedures (date employment will begin, earnings, etc.) must be included.

(C) A statement from the servicemember that he/she intends to reenlist or extend his/her period of active duty or Reserve or National Guard service to a date beyond the 12 month period following the projected loan closing date, and a statement from the servicemember's commanding

officer confirming that the servicemember is eligible to reenlist or extend his/her active duty or Reserve or National Guard service as indicated and that the commanding officer has no reason to believe that such reenlistment or extension will not be granted.

(D) Other unusually strong positive underwriting factors, such as a downpayment of at least 10 percent, significant cash reserves, or clear evidence of strong ties to the community coupled with a nonmilitary spouse's income so high that only minimal income from the active duty servicemember or member of the Reserves or National Guard is needed to qualify.

(iii) Each active-duty member who applies for a loan must be counseled through the use of VA Form 26–0592, Counseling Checklist for Military Homebuyers. Lenders must submit a signed and dated VA Form 26–0592 with each prior approval loan application or automatic loan report involving a borrower on active duty.

(3) *Income reliability*. Income received by the borrower and spouse is to be used only if it can be concluded that the income will continue during the foreseeable future and, thus, should be properly considered in determining ability to meet the mortgage payments. If an employer puts N/A or otherwise declines to complete a verification of employment statement regarding the probability of continued employment, no further action is required of the lender. Reliability will be determined based on the duration of the borrower's current employment together with his or her overall documented employment history. There can be no discounting of income solely because it is derived from an annuity, pension or other retirement benefit, or from part-time employment. However, unless income from overtime work and part-time or second jobs can be accorded a reasonable likelihood that it is continuous and will continue in the foreseeable future, such income should not be used. Generally, the reliability of such income cannot be demonstrated unless the income has continued for 2 years. The hours of duty and other work conditions of the applicant's primary job, and the period of time in which the applicant was employed under such arrangement, must be such as to permit a clear conclusion as to a good probability that overtime or part-time or secondary employment can and will continue. Income from overtime work and part-time jobs not eligible for inclusion as primary income may, if properly verified for at least 12 months, be used to offset the payments due on debts and obligations of an intermediate term, i.e., 6 to 24 months. Such income must be described in the loan file. The amount of any pension or compensation and other income, such as dividends from stocks, interest from bonds, savings accounts, or other deposits, rents, royalties, etc., will be used as primary income if it is reasonable to conclude that such income will continue in the foreseeable future. Otherwise, it may be used only to offset intermediate-term debts, as described in this paragraph. Also, the likely duration of certain military allowances cannot be determined and, therefore, will be used only to offset intermediate-term debts, as described in this paragraph. Such allowances are: Pro-pay, flight or hazard pay, and overseas or combat pay, all of which are subject to periodic review and/or testing of the recipient to ascertain whether eligibility for such pay will continue. Only if it can be shown that such pay has continued for a prolonged period and can be expected to continue because of the nature of the recipient's assigned duties, will such income be considered as primary income. For instance, flight pay verified for a pilot can be regarded as probably continuous and, thus, should be added to the base pay. Income derived from service in the Reserves or National Guard may be used if the applicant has served in such capacity for a period of time sufficient to evidence good probability that such income will continue beyond 12 months. The total period of active and reserve service may be helpful in this regard. Otherwise, such income may be used to offset intermediate-term debts. There are a number of additional income sources whose contingent nature precludes their being considered as available for repayment of a long-term mortgage obligation. Temporary income items such as VA educational allowances and unemployment compensation do not represent stable and reliable income and will not be taken into consideration in determining the ability of the veteran to meet the income requirement of the governing law. As required by the Equal Opportunity Act Amendments of 1976, Public Law 94–239, income from public assistance programs is used to qualify for a loan if it can be determined that the income will probably continue for 3 years or more.

(4) *Tax-exempt income*. Special consideration can be given to verified nontaxable income once it has been established that such income is likely to continue (and remain untaxed) into the foreseeable future. Such income includes certain military allowances, child support payments, workers' compensation benefits, disability retirement payments and certain types of public assistance payments. In such cases, current income tax tables may be used to determine an amount which can be prudently employed to adjust the borrower's actual income. This adjusted or ''grossed up'' income may be used to calculate the monthly debt-to-income ratio, provided the analysis is documented. Only the borrower's actual income may be used to calculate the residual income. Care should be exercised to ensure that the income is in fact tax-exempt.

(5) *Alimony, child support, maintenance, workers' compensation, foster care payments*. (i) If an applicant chooses to reveal income from alimony, child support or maintenance payments (after first having been informed that any such disclosure is voluntary pursuant to the Federal Reserve Board's Regulation B), such payments are considered as income to the extent that the payments are likely to be consistently made. Factors to be considered in determining the likelihood of consistent payments include, but are not limited to: Whether the payments are received pursuant to a written agreement or court decree; the length of time the payments have been received; the regularity of receipt; the availability of procedures to compel payment; and the creditworthiness of the payor, including the credit history of the payor when available under the Fair Credit Reporting Act or other applicable laws. However, the Fair Credit Reporting Act (15 U.S.C. 1681(b)) limits the permissible purposes for which credit reports may be ordered, in the absence of written instructions of the consumer to whom the report relates, to business transactions involving the subject of the credit report or extensions of credit to the subject of the credit report.

(ii) If the applicant chooses to reveal income related to workers' compensation, it will be considered as income to the extent it can be determined such income will continue.

(iii) Income received specifically for the care of any foster child(ren) may be counted as income if documented. Generally, however, such foster care income is to be used only to balance the expenses of caring for the foster child(ren) against any increased residual income requirements.

(6) *Military quarters allowance.* With respect to off-base housing (quarters) allowances for service personnel on active duty, it is the policy of the Department of Defense to utilize available on-base housing when possible. In order for a quarters

allowance to be considered as continuing income, it is necessary that the applicant furnish written authorization from his or her commanding officer for off-base housing. This authorization should verify that quarters will not be made available and that the individual should make permanent arrangements for nonmilitary housing. A Department of Defense form, DD Form 1747, Status of Housing Availability, is used by the Family Housing Office to advise personnel regarding family housing. The applicant's quarters allowance cannot be considered unless item b (Permanent) or d is completed on DD Form 1747, dated October 1990. Of course, if the applicant's income less quarters allowance is sufficient, there is no need for assurance that the applicant has permission to occupy nonmilitary housing provided that a determination can be made that the occupancy requirements of the law will be met. Also, authorization to obtain off-base housing will not be required when certain duty assignments would clearly qualify service personnel with families for quarters allowance. For instance, off-base housing authorizations need not be obtained for service personnel stationed overseas who are not accompanied by their families, recruiters on detached duty, or military personnel stationed in areas where no on-base housing exists. In any case in which no off-base housing authorization is obtained, an explanation of the circumstances justifying its omission must be included with the loan application except when it has been established by the VA facility of jurisdiction that the waiting lists for on-base housing are so long that it is improbable that individuals desiring to purchase off-base housing would be precluded from doing so in the foreseeable future. If stations make such a determination, a release shall be issued to inform lenders.

(7) *Automobile (or similar) allowance.* Generally, automobile allowances are paid to cover specific expenses related to an applicant's employment, and it is appropriate to use such income to offset a corresponding car payment. However, in some instances, such an allowance may exceed the car payment. With proper documentation, income from a car allowance which exceeds the car payment can be counted as effective income. Likewise, any other similar type of allowance which exceeds the specific expense involved may be added to gross income to the extent it is documented to exceed the actual expense.

(8) *Commissions.* When all or a major portion of the veteran's income is derived from commissions, it will be necessary to establish the stability of such income if it is to be considered in the loan analysis for the repayment of the mortgage debt and/or short-term obligations. In order to assess the value of such income, lenders should obtain written verification of the actual amount of commissions paid to date, the basis for the payment of such commissions and when commissions are paid; i.e., monthly, quarterly, semiannually, or annually. Lenders should also obtain signed and dated individual income tax returns, plus applicable schedules, for the previous 2 years, or for whatever additional period is deemed necessary to properly demonstrate a satisfactory earnings record. The length of the veteran's employment in the type of occupation for which commissions are paid is also an important factor in the assessment of the stability of the income. If the veteran has been employed for a relatively short time, the income should not normally be considered stable unless the product or service was the same or closely related to the product or service sold in an immediate prior position. Generally, income from commissions is considered stable when the applicant has been receiving such income for at least 2 years. Less than 2 years of income from commissions cannot usually be considered stable. When an applicant has received income from commissions for less than 1 year, it will rarely be possible to demonstrate that the income is stable for qualifying purposes; such cases would require in-depth development.

(9) *Self-employment.* Generally, income from self-employment is considered stable when the applicant has been in business for at least 2 years. Less than 2 years of income from self-employment cannot usually be considered stable unless the applicant has had previous related employment and/or extensive specialized training. When an applicant has been self-employed less than 1 year, it will rarely be possible to demonstrate that the income is stable for qualifying purposes; such cases would require in-depth development. The following documentation is required for all self-employed borrowers:

(i) A profit-and-loss statement for the prior fiscal year (12-month accounting cycle), plus the period year to date since the end of the last fiscal year (or for whatever shorter period records may be available), and balance sheet based on the financial records. The financial statement must be sufficient for a loan underwriter to determine the necessary information for loan approval and an independent audit (on the veteran and/or the business) by a Certified Public Accountant will be required if necessary for such determination; and

(ii) Copies of signed individual income tax returns, plus all applicable schedules for the previous 2 years, or for whatever additional period is deemed necessary to properly demonstrate a satisfactory earnings record, must be obtained. If the business is a corporation or partnership, copies of signed Federal business income tax returns for the previous two years plus all applicable schedules for the corporation or partnership must be obtained; and

(iii) If the business is a corporation or partnership, a list of all stockholders or partners showing the interest each holds in the business will be required. Some cases may justify a written credit report on the business as well as the applicant. When the business is of an unusual type and it is difficult to determine the probability of its continued operation, explanation as to the function and purpose of the business may be needed from the applicant and/or any other qualified party with the acknowledged expertise to express a valid opinion.

(10) *Recently discharged veterans.* Loan applications received from recently discharged veterans who have little or no employment experience other than their military occupation and from veterans seeking VA-guaranteed loans who have retired after 20 years of active military duty require special attention. The retirement income of the latter veterans in many cases may not be sufficient to meet the statutory income requirements for the loan amount sought. Many have obtained full-time employment and have been employed in their new jobs for a very short time.

(i) It is essential in determining whether veterans in these categories qualify from the income standpoint for the amount of the loan sought, that the facts in respect to their present employment and retirement income be fully developed, and that each case be considered on its individual merits.

(ii) In most cases the veteran's current income or current income plus his or her retirement income is sufficient. The problem lies in determining whether it can be properly concluded that such income level will continue for the foreseeable future. If the veteran's employment status is that of a trainee or an apprentice, this will, of course, be a factor. In cases of the self-employed, the question to be resolved is whether there are reasonable prospects that the business enterprise will be successful and produce the required income. Unless a favorable conclusion can be made, the income from such source

should not be considered in the loan analysis.

(iii) If a recently discharged veteran has no prior employment history and the veteran's verification of employment shows he or she has not been on the job a sufficient time in which to become established, consideration should be given to the duties the veteran performed in the military service. When it can be determined that the duties a veteran performed in the service are similar or are in direct relation to the duties of the applicant's present position, such duties may be construed as adding weight to his or her present employment experience and the income from the veteran's present employment thus may be considered available for qualifying the loan, notwithstanding the fact that the applicant has been on the present job only a short time. This same principle may be applied to veterans recently retired from the service. In addition, when the veteran's income from retirement, in relation to the total of the estimated shelter expense, long-term debts and amount available for family support, is such that only minimal income from employment is necessary to qualify from the income standpoint, it would be proper to resolve the doubt in favor of the veteran. It would be erroneous, however, to give consideration to a veteran's income from employment for a short duration in a job requiring skills for which the applicant has had no training or experience.

(iv) To illustrate the provisions of paragraph (f)(10), it would be proper to use short-term employment income in qualifying a veteran who had experience as an airplane mechanic in the military service and the individual's employment after discharge or retirement from the service is in the same or allied fields; e.g., auto mechanic or machinist. This presumes, however, that the verification of employment included a statement that the veteran was performing the duties of the job satisfactorily, the possibility of continued employment was favorable and that the loan application is eligible in all other respects. An example of nonqualifying experience is that of a veteran who was an Air Force pilot and has been employed in insurance sales on commission for a short time. Most cases, of course, fall somewhere between those extremes. It is for this reason that the facts of each case must be fully developed prior to closing the loan automatically or submitting the case to VA for prior approval.

(11) *Employment of short duration.* The provisions of paragraph (f)(7) of this section are similarly applicable to applicants whose employment is of short duration. Such cases will entail careful consideration of the employer's confirmation of employment, probability of permanency, past employment record, the applicant's qualifications for the position, and previous training, including that received in the military service. In the event that such considerations do not enable a determination that the income from the veteran's current position has a reasonable likelihood of continuance, such income should not be considered in the analysis. Applications received from persons employed in the building trades, or in other occupations affected by climatic conditions, should be supported by documentation evidencing the applicant's total earnings to date and covering a period of not less than 1 year as well as signed and dated copies of complete income tax returns, including all schedules for the past 2 years or for whatever additional period is deemed necessary to properly demonstrate a satisfactory earnings record. If the applicant works out of a union, evidence of the previous year's earnings should be obtained together with a verification of employment from the current employer.

(12) *Rental income*—(i) *Multi-unit subject property.* When the loan pertains to a structure with more than a one-family dwelling unit, the prospective rental income will not be considered unless the veteran can demonstrate a reasonable likelihood of success as a landlord, and sufficient cash reserves are verified to enable the veteran to carry the mortgage loan payments (principal, interest, taxes, and insurance) without assistance from the rental income for a period of at least 6 months. The determination of the veteran's likelihood of success as a landlord will be based on documentation of any prior experience in managing rental units or other collection activities. The amount of rental income to be used in the loan analysis will be based on 75 percent of the amount indicated on the lease or rental agreement, unless a greater percentage can be documented.

(ii) *Rental of existing home.* Proposed rental of a veteran's existing property may be used to offset the mortgage payment on that property, provided there is no indication that the property will be difficult to rent. If available, a copy of the rental agreement should be obtained. It is the responsibility of the loan underwriter to be aware of the condition of the local rental market. For instance, in areas where the rental market is very strong the absence of a lease should not automatically prohibit the offset of the mortgage by the proposed rental income.

(iii) *Other rental property.* If income from rental property will be used to qualify for the new loan, the documentation required of a self-employed applicant should be obtained together with evidence of cash reserves equaling 3 months PITI on the rental property. As for any self-employed earnings (see paragraph (f)(7) of this section), depreciation claimed may be added back in as income. In the case of a veteran who has no experience as a landlord, it is unlikely that the income from a rental property may be used to qualify for the new loan.

(13) *Taxes and other deductions.* Deductions to be applied for Federal income taxes and Social Security may be obtained from the Employer's Tax Guide (Circular E) issued by the Internal Revenue Service (IRS). (For veterans receiving a mortgage credit certificate (MCC), see paragraph (f)(14) of this section.) Any State or local taxes should be estimated or obtained from charts similar to those provided by IRS which may be available in those states with withholding taxes. A determination of the amount paid or withheld for retirement purposes should be made and used when calculating deductions from gross income. In determining whether a veteran-applicant meets the income criteria for a loan, some consideration may be given to the potential tax benefits the veteran will realize if the loan is approved. This can be done by using the instructions and worksheet portion of IRS Form W–4, Employee's Withholding Allowance Certificate, to compute the total number of permissible withholding allowances. That number can then be used when referring to IRS Circular E and any appropriate similar State withholding charts to arrive at the amount of Federal and State income tax to be deducted from gross income.

(14) *Mortgage credit certificates.* (i) The Internal Revenue Code (26 U.S.C.) as amended by the Tax Reform Act of 1984, allows states and other political subdivisions to trade in all or part of their authority to issue mortgage revenue bonds for authority to issue MCCs. Veterans who are recipients of MCCs may realize a significant reduction in their income tax liability by receiving a Federal tax credit for a percentage of their mortgage interest payment on debt incurred on or after January 1, 1985.

(ii) Lenders must provide a copy of the MCC to VA with the home loan application. The MCC will specify the rate of credit allowed and the amount of certified indebtedness; i.e., the

indebtedness incurred by the veteran to acquire a principal residence or as a qualified home improvement or rehabilitation loan.

(iii) For credit underwriting purposes, the amount of tax credit allowed to a veteran under an MCC will be treated as a reduction in the monthly Federal income tax. For example, a veteran having a $600 monthly interest payment and an MCC providing a 30-percent tax credit would receive a $180 (30 percent×$600) tax credit each month. However, because the annual tax credit, which amounts to $2,160 (12×$180), exceeds $2,000 and is based on a 30-percent credit rate, the maximum tax credit the veteran can receive is limited to $2,000 per year (Pub. L. 98–369) or $167 per month ($2,000/12). As a consequence of the tax credit, the interest on which a deduction can be taken will be reduced by the amount of the tax credit to $433 ($600 − $167). This reduction should also be reflected when calculating Federal income tax.

(iv) For underwriting purposes, the amount of the tax credit is limited to the amount of the veteran's maximum tax liability. If, in the example in paragraph (f)(14)(iii) of this section, the veteran's tax liability for the year were only $1,500, the monthly tax credit would be limited to $125 ($1,500/12).

(g) *Credit.* The conclusion reached as to whether or not the veteran and spouse are satisfactory credit risks must also be based on a careful analysis of the available credit data. Regulation B (12 CFR part 202), promulgated by the Federal Reserve Board pursuant to the Equal Credit Opportunity Act, requires that lenders, in evaluating creditworthiness, shall consider, on the applicant's request, the credit history, when available, of any account reported in the name of the applicant's spouse or former spouse which the applicant can demonstrate accurately reflects the applicant's creditworthiness. In other than community property states, if the spouse will not be contractually obligated on the loan, Regulation B prohibits any request for or consideration of information about the spouse concerning income, employment, assets or liabilities. In community property states, information concerning a spouse may be requested and considered in the same manner as that for the applicant.

(1) *Adverse data.* If the analysis develops any derogatory credit information and, despite such facts, it is determined that the veteran and spouse are satisfactory credit risks, the basis for the decision must be explained. If a veteran and spouse have debts outstanding which have not been paid timely, or which they have refused to pay, the fact that the outstanding debts are paid after the acceptability of the credit is questioned or in anticipation of applying for new credit does not, of course, alter the fact that the record for paying debts has been unsatisfactory. With respect to unpaid debts, lenders may take into consideration a veteran's claim of bona fide or legal defenses. Such defenses are not applicable when the debt has been reduced to judgment. Where a collection account has been established, if it is determined that the borrower is a satisfactory credit risk, it is not mandatory that such an account be paid off in order for a loan to be approved. Court-ordered judgments, however, must be paid off before a new loan is approved.

(2) *Bankruptcy.* When the credit information shows that the borrower or spouse has been discharged in bankruptcy under the ''straight'' liquidation and discharge provisions of the bankruptcy law, this would not in itself disqualify the loan. However, in such cases it is necessary to develop complete information as to the facts and circumstances concerning the bankruptcy. Generally speaking, when the borrower or spouse, as the case may be, has been regularly employed (not self-employed) and has been discharged in bankruptcy within the last one to two years, it probably would not be possible to determine that the borrower or spouse is a satisfactory credit risk unless both of the following requirements are satisfied:

(i) The borrower or spouse has obtained credit subsequent to the bankruptcy and has met the credit payments in a satisfactory manner over a continued period; and

(ii) The bankruptcy was caused by circumstances beyond the control of the borrower or spouse, e.g., unemployment, prolonged strikes, medical bills not covered by insurance. Divorce is not generally viewed as beyond the control of the borrower and/or spouse. The circumstances alleged must be verified. If a borrower or spouse is self-employed, has been adjudicated bankrupt, and subsequently obtains a permanent position, a finding as to satisfactory credit risk may be made provided there is no derogatory credit information prior to self-employment, there is no derogatory credit information subsequent to the bankruptcy, and the failure of the business was not due to misconduct. If a borrower or spouse has been discharged in bankruptcy within the past 12 months, it will not generally be possible to determine that the borrower or spouse is a satisfactory credit risk.

(3) *Petition under Chapter 13 of Bankruptcy Code.* A petition under chapter 13 of the Bankruptcy Code (11 U.S.C.) filed by the borrower or spouse is indicative of an effort to pay their creditors. Some plans may provide for full payment of debts while others arrange for payment of scaled-down debts. Regular payments are made to a court-appointed trustee over a 2- to 3-year period (or up to 5 years in some cases). When the borrowers have made all payments in a satisfactory manner, they may be considered as having reestablished satisfactory credit. When they apply for a home loan before completion of the payout period, favorable consideration may nevertheless be given if at least 12 months' worth of payments have been made satisfactorily and the Trustee or Bankruptcy Judge approves of the new credit.

(4) *Foreclosures.* (i) When the credit information shows that the veteran or spouse has had a foreclosure on a prior mortgage; e.g., a VA-guaranteed or HUD-insured mortgage, this will not in itself disqualify the borrower from obtaining the loan. Lenders and field station personnel should refer to the preceding guidelines on bankruptcies for cases involving foreclosures. As with a borrower who has been adjudicated bankrupt, it is necessary to develop complete information as to the facts and circumstances of the foreclosure.

(ii) When VA pays a claim on a VA-guaranteed loan as a result of a foreclosure, the original veteran may be required to repay any loss to the Government. In some instances VA may waive the veteran's debt, in part or totally, based on the facts and circumstances of the case. However, guaranty entitlement cannot be restored unless the Government's loss has been repaid in full, regardless of whether or not the debt has been waived, compromised, or discharged in bankruptcy. Therefore, a veteran who is seeking a new VA loan after having experienced a foreclosure on a prior VA loan will in most cases have only remaining entitlement to apply to the new loan. The lender should assure that the veteran has sufficient entitlement for its secondary marketing purposes.

(5) *Federal debts.* An applicant for a Federally-assisted loan will not be considered a satisfactory credit risk for such loan if the applicant is presently delinquent or in default on any debt to the Federal Government, e.g., a Small Business Administration loan, a U.S. Guaranteed Student loan, a debt to the Public Health Service, or where there is a judgment lien against the applicant's property for a debt owed to the

Government. The applicant may not be approved for the loan until the delinquent account has been brought current or satisfactory arrangements have been made between the borrower and the Federal agency owed, or the judgment is paid or otherwise satisfied. Of course, the applicant must also be able to otherwise qualify for the loan from an income and remaining credit standpoint. Refinancing under VA's interest rate reduction refinancing provisions, however, is allowed even if the borrower is delinquent on the VA guaranteed mortgage being refinanced. Prior approval processing is required in such cases.

(6) *Absence of credit history*. The fact that recently discharged veterans may have had no opportunity to develop a credit history will not preclude a determination of satisfactory credit. Similarly, other loan applicants may not have established credit histories as a result of a preference for purchasing consumer items with cash rather than credit. There are also cases in which individuals may be genuinely wary of acquiring new obligations following bankruptcy, consumer credit counseling (debt proration), or other disruptive credit occurrence. The absence of the credit history in these cases will not generally be viewed as an adverse factor in credit underwriting. However, before a favorable decision is made for cases involving bankruptcies or other derogatory credit factors, efforts should be made to develop evidence of timely payment of non-installment debts such as rent and utilities. It is anticipated that this special consideration in the absence of a credit history following bankruptcy would be the rare case and generally confined to bankruptcies that occurred over 3 years ago.

(7) *Consumer credit counseling plan*. If a veteran, or veteran and spouse, have prior adverse credit and are participating in a Consumer Credit Counseling plan, they may be determined to be a satisfactory credit risk if they demonstrate 12 months' satisfactory payments and the counseling agency approves the new credit. If a veteran, or veteran and spouse, have good prior credit and are participating in a Consumer Credit Counseling plan, such participation is to be considered a neutral factor, or even a positive factor, in determining creditworthiness.

(8) *Re-establishment of satisfactory credit.* In circumstances not involving bankruptcy, satisfactory credit is generally considered to be reestablished after the veteran, or veteran and spouse, have made satisfactory payments for 12 months after the date of the last derogatory credit item.

(9) *Long-term v. short-term debts.* All known debts and obligations including any alimony and/or child support payments of the borrower and spouse must be documented. Significant liabilities, to be deducted from the total income in determining ability to meet the mortgage payments are accounts that, generally, are of a relatively long term, i.e., 10 months or over. Other accounts for terms of less than 10 months must, of course, be considered in determining ability to meet family expenses. Certainly, any severe impact on the family's resources for any period of time must be considered in the loan analysis. For example, monthly payments of $300 on an auto loan with a remaining balance of $1,500 would be included in those obligations to be deducted from the total income regardless of the fact that the account can be expected to pay out in 5 months. It is clear that the applicant will, in this case, continue to carry the burden of those $300 payments for the first, most critical months of the home loan.

(10) *Requirements for verification*. If the credit investigation reveals debts or obligations of a material nature which were not divulged by the applicant, lenders must be certain to obtain clarification as to the status of such debts from the borrower. A proper analysis is obviously not possible unless there is total correlation between the obligations claimed by the borrower and those revealed by a credit report or deposit verification. Conversely, significant debts and obligations reported by the borrower must be dated. If the credit report fails to provide necessary information on such accounts, lenders will be expected to obtain their own verifications of those debts directly from the creditors. Credit reports and verifications must be no more than 120 days old (180 days for new construction) to be considered valid. For loans closed automatically, this requirement will be considered satisfied if the date of the credit report or verification is within 120 days (180 days for new construction) of the date the note is signed. For prior approval loans, this requirement will be considered satisfied if the date of the credit report or verification is within 120 days of the date of the application is received by VA. Of major significance are the applicant's rental history and outstanding or recently retired mortgages, if any, particularly prior VA loans. Lenders should be sure ratings on such accounts are obtained; a written explanation is required when ratings are not available. A determination is necessary as to whether alimony and/or child support payments are required. Verification of the amount of such obligations should be obtained, although documentation concerning an applicant's divorce should not be obtained automatically unless it is necessary to verify the amount of any alimony or child support liability indicated by the applicant. If in the routine course of processing the loan application, however, direct evidence is received (e.g., from the credit report) that an obligation to pay alimony or child support exists (as opposed to mere evidence that the veteran was previously divorced), the discrepancy between the loan application and credit report can and should be fully resolved in the same manner as any other such discrepancy would be handled. When a pay stub or leave-and-earnings statement indicates an allotment, the lender must investigate the nature of the allotment(s) to determine whether the allotment is related to a debt. Debts assigned to an ex-spouse by a divorce decree will not generally be charged against a veteran-borrower.

(11) *Job-related expenses.* Known job-related expenses should be documented. This will include costs for any dependent care, significant commuting costs, etc. When a family's circumstances are such that dependent care arrangements would probably be necessary, it is important to determine the cost of such services in order to arrive at an accurate total of deductions.

(12) *Credit reports.* Credit reports obtained by lenders on VA-guaranteed loan applications must be either a three-file Merged Credit Report (MCR) or a Residential Mortgage Credit Report (RMCR). If used, the RMCR must meet the standards formulated jointly by the Department of Veterans Affairs, Federal National Mortgage Association, Federal Home Loan Mortgage Corporation, Federal Housing Administration, Farmers Home Administration, credit repositories, repository affiliated consumer reporting agencies and independent consumer reporting agencies. All credit reports obtained by the lender must be submitted to VA.

(h) *Borrower's personal and financial status.* The number and ages of dependents have an important bearing on whether income after deduction of fixed charges is sufficient to support the family. Type and duration of employment of both the borrower and spouse are important as an indication of stability of their employment. The amount of liquid assets owned by the borrower or spouse, or both, is an important factor in determining that they have sufficient funds to close the

loan, as well as being significant in analyzing the overall qualifications for the loan. (It is imperative that adequate cash assets from the veteran's own resources are verified to allow the payment (see § 36.4336(a)(3)) of any difference between the sales price of the property and the loan amount, in addition to that necessary to cover closing costs, if the sales price exceeds the reasonable value established by VA.) Verifications must be no more than 120 days old (180 days for new construction) to be considered valid. For loans closed on the automatic basis, this requirement will be considered satisfied if the date of the deposit verification is within 120 days (180 days for new construction) of the date of the veteran's application to the lender. For prior approval loans, this requirement will be considered satisfied if the verification of employment is dated within 120 days of the date the application is received by VA. Current monthly rental or other housing expense is an important consideration when compared to that to be undertaken in connection with the contemplated housing purchase.

* * * * *

(j) *Lender responsibility.* (1) Lenders are fully responsible for developing all credit information; i.e., for obtaining verifications of employment and deposit, credit reports, and for the accuracy of the information contained in the loan application.

(2) Verifications of employment and deposits, and requests for credit reports and/or credit information must be initiated and received by the lender.

(3) In cases where the real estate broker/agent or any other party requests any of this information, the report(s) must be returned directly to the lender. This fact must be disclosed by appropriately completing the required certification on the loan application or report and the parties must be identified as agents of the lender.

(4) Where the lender relies on other parties to secure any of the credit or employment information or otherwise accepts such information obtained by any other party, such parties shall be construed for purposes of the submission of the loan documents to VA to be authorized agents of the lender, regardless of the actual relationship between such parties and the lender, even if disclosure is not provided to VA under paragraph (j)(3) of this section. Any negligent or willful misrepresentation by such parties shall be imputed to the lender as if the lender had processed those documents and the lender shall remain responsible for the quality and accuracy of the information provided to VA.

(5) All credit reports secured by the lender or other parties as identified in paragraphs (j)(3) and (j)(4) of this section shall be provided to VA. If updated credit reports reflect materially different information than that in other reports, such discrepancies must be explained by the lender and the ultimate decision as to the effects of the discrepancy upon the loan application fully addressed by the underwriter.

(k) *Lender certification.* Lenders originating loans are responsible for determining and certifying to VA on the appropriate application or closing form that the loan meets all statutory and regulatory requirements. Lenders will affirmatively certify that loans were made in full compliance with the law and loan guaranty regulations as prescribed in this section.

(1) *Definitions.* The definitions contained in part 42 of this title and the following definitions are applicable in this section.

(i) *Another appropriate amount.* In determining the appropriate amount of a lender's civil penalty in cases where the Secretary has not sustained a loss or where two times the amount of the Secretary's loss on the loan involved does not exceed $10,000, the Secretary shall consider:

(A) The materiality and importance of the false certification to the determination to issue the guaranty or to approve the assumption;

(B) The frequency and past pattern of such false certifications by the lender; and

(C) Any exculpatory or mitigating circumstances.

(ii) *Complaint* includes the assessment of liability served pursuant to this section.

(iii) *Defendant* means a lender named in the complaint.

(iv) *Lender* includes the holder approving loan assumptions pursuant to 38 U.S.C. 3714.

(2) *Procedures for certification.* (i) As a condition to VA issuance of a loan guaranty on all loans closed on or after October 27, 1994, and as a prerequisite to an effective loan assumption on all loans assumed pursuant to 38 U.S.C. 3714 on or after November 17, 1997, the following certification shall accompany each loan closing or assumption package:

> The undersigned lender certifies that the (loan) (assumption) application, all verifications of employment, deposit, and other income and credit verification documents have been processed in compliance with 38 CFR part 36; that all credit reports obtained or generated in connection with the processing of this borrower's (loan) (assumption) application have been provided to VA; that, to the best of the undersigned lender's knowledge and belief the (loan) (assumption) meets the underwriting standards recited in chapter 37 of title 38 United States Code and 38 CFR part 36; and that all information provided in support of this (loan) (assumption) is true, complete and accurate to the best of the undersigned lender's knowledge and belief.

(ii) The certification shall be executed by an officer of the lender authorized to execute documents and act on behalf of the lender.

(3) Any lender who knowingly and willfully makes a false certification required pursuant to § 36.4337(k)(2) shall be liable to the United States Government for a civil penalty equal to two times the amount of the Secretary's loss on the loan involved or to another appropriate amount, not to exceed $10,000, whichever is greater.

(l) *Assessment of liability.* (1) Upon an assessment confirmed by the Under Secretary for Benefits, in consultation with the Investigating Official, that a certification, as required in this section, is false, a report of findings of the Under Secretary for Benefits shall be submitted to the Reviewing Official setting forth:

(i) The evidence that supports the allegations of a false certification and of liability;

(ii) A description of the claims or statements upon which the allegations of liability are based;

(iii) The amount of the VA demand to be made; and

(iv) Any exculpatory or mitigating circumstances that may relate to the certification.

(2) The Reviewing Official shall review all of the information provided and will either inform the Under Secretary for Benefits and the Investigating Official that there is not adequate evidence, that the lender is liable, or serve a complaint on the lender stating:

(i) The allegations of a false certification and of liability;

(ii) The amount being assessed by the Secretary and the basis for the amount assessed;

(iii) Instructions on how to satisfy the assessment and how to file an answer to request a hearing, including a specific statement of the lender's right to request a hearing by filing an answer and to be represented by counsel; and

(iv) That failure to file an answer within 30 days of the complaint will result in the imposition of the assessment without right to appeal the assessment to the Secretary.

* * * * *

(n) *Additional remedies.* Any assessment under this section may be in

addition to other remedies available to VA, such as debarment and suspension pursuant to 38 U.S.C. 3704 and part 44 of this title or loss of automatic processing authority pursuant to 38 U.S.C. 3702, or other actions by the Government under any other law including but not limited to title 18 U.S.C. and 31 U.S.C. 3732.

(The information collection requirements in this section have been approved by the Office of Management and Budget under control numbers 2900–0521)

(Authority: 38 U.S.C. 3703, 3710)

[FR Doc. 97–27564 Filed 10–16–97; 8:45 am]

BILLING CODE 8320–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MM Docket No. 97–154; RM–9116]

Radio Broadcasting Services; Newaygo, MI

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: This document allots Channel 223A to Newaygo, Michigan, as that community's first local FM broadcast service in response to a petition filed by Robert R. Moore, Jr. *See* 62 FR 38246, July 17, 1997. The coordinates for Channel 223A at Newaygo are 43–22–12 and 85–51–49. There is a site restriction 7.6 kilometers (4.7 miles) southwest of the communtiy. Since Newaygo is located within 320 kilometers (200 miles) of the U.S.-Canadian border, concurrence of the Canadian government has been obtained for this allotment. With this action, this proceeding is terminated.

DATES: Effective November 17, 1997. The window period for filing applications for Channel 223A at Newaygo, Michigan, will open on November 17, 1997, and close on December 18, 1997.

FOR FURTHER INFORMATION CONTACT: Kathleen Scheuerle, Mass Media Bureau, (202) 418–2180.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Report and Order, MM Docket No. 97–154, adopted September 24, 1997, and released October 3, 1997. The full text of this Commission decision is available for inspection and copying during normal business hours in the Commission's Reference Center (Room 239), 1919 M Street, NW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractors, International Transcription Services, Inc., 1231 20th Street, NW., Washington, DC. 20036, (202) 857–3800, facsimile (202) 857–3805.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

Part 73 of title 47 of the Code of Federal Regulations is amended as follows:

PART 73—[AMENDED]

1. The authority citation for Part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303, 334, 336.

§ 73.202 [Amended]

2. Section 73.202(b), the Table of FM Allotments under Michigan, is amended by adding Newaygo, Channel 223A.

Federal Communications Commission.

John A. Karousos,

Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 97–27514 Filed 10–16–97; 8:45 am]

BILLING CODE 6712–01–F

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 961126334–7025–02; I.D.100997A]

Fisheries of the Exclusive Economic Zone Off Alaska; Pacific cod in Central Regulatory Area of the Gulf of Alaska

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Reallocation.

SUMMARY: NMFS is reallocating the projected unused amount of Pacific cod from vessels catching Pacific cod for processing by the offshore component to vessels catching Pacific cod for processing by the inshore component in the Central Regulatory Area of the Gulf of Alaska (GOA). This action is necessary to allow the 1997 total allowable catch (TAC) of Pacific cod to be harvested.

DATES: Effective 1200 hrs, Alaska local time (A.l.t.), October 10, 1997, until 2400 hrs, A.l.t., December 31, 1997.

FOR FURTHER INFORMATION CONTACT: Andrew N. Smoker, 907–586-7228.

SUPPLEMENTARY INFORMATION: The groundfish fishery in the GOA exclusive economic zone is managed by NMFS according to the Fishery Management Plan for Groundfish of the Gulf of Alaska (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management Act. Fishing by U.S. vessels is governed by regulations implementing the FMP at subpart H of 50 CFR part 600 and 50 CFR part 679.

The Administrator, Alaska Region, NMFS, has determined that vessels catching Pacific cod for processing by the offshore component will not be able to harvest 3,000 metric tons (mt) of Pacific cod allocated to those vessels under § 679.20(a)(6)(iii). As of October 4, 1997, NMFS estimates 4,091 mt remain in the offshore component's allocation of the 1997 Central GOA Pacific cod TAC and projects that vessels catching Pacific cod for processing by the offshore component will take 1,091 mt during the remainder of 1997.

Therefore, in accordance with § 679.20(a)(6)(v)(C), NMFS is apportioning the projected unused amount, 3,000 mt of Pacific cod, from vessels catching Pacific cod for processing by the offshore component to vessels catching Pacific cod for processing by the inshore component.

Classification

This action is taken under 50 CFR 679.20, and is exempt from OMB review under E.O. 12866.

All other closures remain in full force and effect. This action responds to the best available information recently obtained from the fishery. It must be implemented immediately in order to allow full utilization of the Pacific cod TAC. Providing prior notice and an opportunity for public comment is impracticable and contrary to the public interest. Further delay would only disrupt the FMP's objective of providing a portion of the Pacific cod TAC for vessels catching Pacific cod for processing by the inshore component in the GOA. Without this action, the Pacific cod allocation for vessels catching Pacific cod for processing by the offshore component in the GOA would be underharvested. NMFS finds for good cause that the implementation of this action cannot be delayed for 30 days. Accordingly, under 5 U.S.C. 553(d), a delay in the effective date is hereby waived.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: October 9, 1997.

Bruce C. Morehead,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 97–27521 Filed 10–10–97; 4:23 pm]

BILLING CODE 3510–22–F

Proposed Rules

Federal Register
Vol. 62, No. 201
Friday, October 17, 1997

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

NUCLEAR REGULATORY COMMISSION

10 CFR Part 50

RIN 3150–AF73

Codes and Standards; IEEE National Consensus Standard

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The Nuclear Regulatory Commission is amending its regulations to incorporate by reference IEEE Std 603–1991, a national consensus standard for power, instrumentation, and control portions of safety systems in nuclear power plants. This action is necessary to endorse the latest version of this national consensus standard in NRC's regulations, and replace an IEEE Standard currently endorsed in the NRC's regulations which has been withdrawn by the IEEE.

DATES: Comments on the proposed rule must be received on or before December 1, 1997.

ADDRESSES: Mail comments to: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; Attention: Rulemakings and Adjudications Staff. Hand deliver comments to 11555 Rockville Pike, Rockville, Maryland, between 7:30 a.m. and 4:15 p.m. on Federal workdays.

Copies of any comments received may be examined at the NRC Public Document Room, 2120 L Street, NW, (lower level), Washington, DC.

For information on submitting comments electronically, see the discussion under Electronic Access in the Supplementary Information Section.

FOR FURTHER INFORMATION CONTACT: Satish K. Aggarwal, Senior Program Manager, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Telephone (301) 415–6005, Fax (301) 415–5074, E-mail: SKA@NRC.GOV

SUPPLEMENTARY INFORMATION: For additional information, see the direct final rule published in the Rules and Regulations Section of this **Federal Register**.

Procedural Background

Because NRC considers this rulemaking noncontroversial, we are publishing this proposed rule concurrently as a direct final rule. The direct final rule will become effective on January 1, 1998. However, if the NRC receives significant adverse comments on the direct final rule by December 1, 1997, then the NRC will publish a document that withdraws the direct final rule. If the direct final rule is withdrawn, the NRC will address the comments received in a subsequent final rule. The NRC will not initiate a second comment period on this action in the event the direct final rule is withdrawn.

Electronic Access

You may also provide comments via the NRC's interactive rulemaking website through the NRC home page (http;//www.nrc.gov). This site provides the availability to upload comments as files (any format), if your web browser supports that function. For information about the interactive rulemaking website, contact Ms. Carol Gallagher, (301) 415–5905 (e-mail: CAG@nrc.gov).

List of Subjects in 10 CFR Part 50

Antitrust, Classified Information, Criminal penalties, Fire protection, Incorporation by reference, Intergovernmental relations, Nuclear power plants and reactors, Radiation protection, Reactor siting criteria, and Reporting and recordkeeping requirements.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended, the Energy Reorganizations Act of 1974, as amended, and 5 U.S.C. 552 and 553, the NRC is adopting the following amendment to 10 CFR part 50.

PART 50—DOMESTIC LICENSING OF PRODUCTION AND UTILIZATION FACILITIES

1. The authority citation for part 50 continues to read as follows:

Authority: Secs. 102, 103, 104, 105, 161, 182, 183, 186, 189, 68 Stat. 936, 937, 938, 948, 953, 954, 955, 956, as amended, sec. 234, 83 Stat. 1244, as amended (42 U.S.C. 2132, 2133, 2134, 2135, 2201, 2232, 2233, 2236, 2239, 2282); secs. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846).

Section 50.7 also issued under Pub. L. 95–601, sec. 10, 92 Stat. 2951 (42 U.S.C. 5851). Section 50.10 also issued under secs. 101, 185, 68 Stat. 955 as amended (42 U.S.C. 2131, 2235), sec. 102, Pub. L. 91–190, 83 Stat. 853 (42 U.S.C. 4332). Sections 50.13, and 50.54 (dd), and 50.103 also issued under sec. 108, 68 Stat. 939, as amended (42 U.S.C. 2138), Sections 50.23, 50.35, 50.55, and 50.56 also issued under sec. 185, 68 Stat. 955 (42 U.S.C. 2235), Sections 50.33a, 50.55a and Appendix Q also issued under sec. 102, Pub. L. 91–190, 83 Stat. 853 (42 U.S.C. 4332). Sections 50.34 and 50.54 also issued under sec. 204, 88 Stat. 1245 (42 U.S.C. 5844). Sections 50.58, 50.91, and 50.92 also issued under Pub. L. 97–415, 96 Stat. 2073 (42 U.S.C. 2239). Section 50.78 also issued under sec. 122, 68 Stat. 939 (42 U.S.C. 2152). Sections 50.80—50.81 also issued under sec. 184, 68 Stat. 954, as amended (42 U.S.C. 2234). Appendix F also issued under sec. 187, 68 Stat. 955 (42 U.S.C. 2237).

2. In § 50.55a, paragraph (h) is revised to read as follows:

§ 50.55a Codes and standards.

* * * * *

(h) *Protection and Safety Systems.* (1) IEEE Std. 603–1991, including the correction sheet dated January 30, 1995, which is referenced in paragraph (h)(3), are approved for incorporation by reference by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A notice of any changes made to the material incorporated by reference will be published in the **Federal Register**. Copies of IEEE Std. 603–1991 may be purchased from the Institute of Electrical and Electronics Engineers Service Center, 445 Hoes Lane, Piscataway, NJ 08855. It is also available for inspection at the NRC Library, 11545 Rockville Pike, Rockville, MD 20852–2738, and at the Office of the Federal Register, 800 North Capital Street, NW, Suite 700, Washington, DC. IEEE Std. 279, which is referenced in paragraph (h)(2) of this section was approved for incorporation by reference by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51. Copies of this standard are also available as indicated for IEEE Std. 603–1991.

(2) Definitions.

(i) For purposes of this paragraph the terms ''protection systems,'' ''safety

systems,'' and ''safety-related systems'' are synonymous.

(ii) Changes to protection systems include modification, augmentation or replacement of protection systems permitted by license amendments, changes made to protection systems by licensees pursuant to 10 CFR 50.59, and plant specific departures from a design certification rule under 10 CFR part 52.

(3) Protection systems. For nuclear power plants with construction permits issued after January 1, 1971, but prior to January 1, 1998, protection systems must meet the requirements set forth in either the Institute of Electrical and Electronics Engineers (IEEE) Std. 279, ''Criteria for Protection Systems for Nuclear Power Generating Stations,'' or in IEEE Std. 603–1991, ''Criteria for Safety Systems for Nuclear Power Generating Stations,'' and the correction sheet dated January 30, 1995. However, changes to protection systems initiated on or after January 1, 1998 must meet the requirements set forth in IEEE Std. 603–1991, and the correction sheet dated January 30, 1995.

(4) Safety systems. For construction permits, operating licenses, final design approvals, design certifications and combined licenses issued on or after January 1, 1998, safety systems must meet the requirements set forth in IEEE Std. 603–1991, and the correction sheet, dated January 30, 1995.

Dated at Rockville, Maryland, this 9th day of October, 1997.

For the Nuclear Regulatory Commission.

John C. Hoyle,

Secretary of the Commission.

[FR Doc. 97–27419 Filed 10–16–97; 8:45 am]

BILLING CODE 7590–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 97–NM–245–AD]

RIN 2120–AA64

Airworthiness Directives; Fokker Model F28 Mark 0070 and Mark 0100 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes the adoption of a new airworthiness directive (AD) that is applicable to certain Fokker Model F28 Mark 0070 and Mark 0100 series airplanes. This proposal would require replacement of the operating handles of the overwing emergency exits with improved handles that have self-illumination. This proposal is prompted by issuance of mandatory continuing airworthiness information by a foreign civil airworthiness authority. The actions specified by the proposed AD are intended to ensure that the operating handles of the overwing emergency exits are clearly visible during an emergency evacuation.

DATES: Comments must be received by November 28, 1997.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–103, Attention: Rules Docket No. 97–NM–245–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056. Comments may be inspected at this location between 9:00 a.m. and 3:00 p.m., Monday through Friday, except Federal holidays.

The service information referenced in the proposed rule may be obtained from Fokker Service B.V., Technical Support Department, P.O. Box 75047, 1117 ZN Schiphol Airport, The Netherlands. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington.

FOR FURTHER INFORMATION CONTACT: Tim Dulin, Aerospace Engineer, Standardization Branch, ANM–113, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 227–2141; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications shall identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained in this notice may be changed in light of the comments received.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposed rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report summarizing each FAA-public contact concerned with the substance of this proposal will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket Number 97–NM–245–AD.'' The postcard will be date stamped and returned to the commenter.

Availability of NPRMs

Any person may obtain a copy of this NPRM by submitting a request to the FAA, Transport Airplane Directorate, ANM–103, Attention: Rules Docket No. 97–NM–245–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056.

Discussion

The Rijksluchtvaartdienst (RLD), which is the airworthiness authority for the Netherlands, notified the FAA that an unsafe condition may exist on certain Fokker Model F28 Mark 0070 and Mark 0100 series airplanes. The RLD advises that the operating handles of the overwing emergency exits installed on Fokker Model F28 Mark 0070 and Mark 0100 series airplanes equipped with the new ''Jetline'' interior do not meet the illumination requirements of section 25.811(e) of the Federal Aviation Regulations [14 CFR 25.811(e)]. Section 25.811(e) requires the handles to be either conspicuously located and well illuminated, or self-illuminated with an initial brightness of at least 160 microlamberts. The operating handles of the overwing emergency exits installed on these airplanes do not have adequate illumination, and, therefore, the handles may not be clearly visible in emergency conditions. This condition, if not corrected, could result in reduced ability to evacuate the airplane during an emergency.

Explanation of Relevant Service Information

Fokker has issued Service Bulletin SBF100–52–060, dated October 10, 1995, which describes procedures for replacement of the operating handles of the overwing emergency exits with improved operating handles that have self-illumination. Accomplishment of the actions specified in the service bulletin is intended to adequately address the identified unsafe condition. The RLD classified this service bulletin as mandatory and issued Netherlands airworthiness directive BLA 1995–104(A), dated October 31, 1995, in order to assure the continued airworthiness of these airplanes in the Netherlands.

FAA's Conclusions

These airplane models are manufactured in the Netherlands and are type certificated for operation in the United States under the provisions of section 21.29 of the Federal Aviation Regulations (14 CFR 21.29) and the applicable bilateral airworthiness agreement. Pursuant to this bilateral airworthiness agreement, the RLD has kept the FAA informed of the situation described above. The FAA has examined the findings of the RLD, reviewed all available information, and determined that AD action is necessary for products of this type design that are certificated for operation in the United States.

Explanation of Requirements of Proposed Rule

Since an unsafe condition has been identified that is likely to exist or develop on other airplanes of the same type design registered in the United States, the proposed AD would require accomplishment of the actions specified in the service bulletin described previously.

Cost Impact

The FAA estimates that 127 Fokker Model F28 Mark 0100 series airplanes and 4 Fokker Model F28 Mark 0070 series airplanes of U.S. registry would be affected by this proposed AD, that it would take approximately 3 work hours per airplane to accomplish the proposed actions, and that the average labor rate is $60 per work hour. Required parts would be provided by the manufacturer at no cost to operators. Based on these figures, the cost impact of the proposed AD on U.S. operators is estimated to be $23,580, or $180 per airplane.

The cost impact figure discussed above is based on assumptions that no operator has yet accomplished any of the proposed requirements of this AD action, and that no operator would accomplish those actions in the future if this AD were not adopted.

Regulatory Impact

The regulations proposed herein would not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this proposal would not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this proposed regulation (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the draft regulatory evaluation prepared for this action is contained in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption **ADDRESSES.**

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

Fokker: Docket 97-NM–245-AD.

Applicability: Model F28 Mark 0070 and Mark 0100 series airplanes, as listed in Fokker Service Bulletin SBF100–52–060, dated October 10, 1995; certificated in any category.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been otherwise modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (b) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

To ensure that the operating handles of the overwing emergency exits are clearly visible during an emergency evacuation, accomplish the following:

(a) Within 12 months after the effective date of this AD, remove the operating handle assemblies of the overwing emergency exits, having part number (P/N) D32965–403, and install new self-illuminating handle assemblies, having P/N D32965–407, in accordance with Fokker Service Bulletin SBF100–52–060, dated October 10, 1995.

(b) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Standardization Branch, ANM–113, FAA, Transport Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Standardization Branch, ANM–113.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Standardization Branch, ANM–113.

(c) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

Note 3: The subject of this AD is addressed in Netherlands airworthiness directive BLA 1995–104 (A), dated October 31, 1995.

Issued in Renton, Washington, on October 10, 1997.

James V. Devany,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 97–27580 Filed 10–16–97; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 97–SW–01–AD]

Airworthiness Directives; Robinson Helicopter Company Model R44 Helicopters

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes the adoption of a new airworthiness directive (AD) that is applicable to Robinson Helicopter Company (Robinson) Model R44 helicopters. This proposal would require removing and replacing the cyclic control pilot's grip assembly (grip assembly) with an airworthy grip assembly. This proposal is prompted by a report of a crack in the welded corner of a grip assembly. The actions specified by the proposed AD are intended to prevent use of a grip assembly that may crack, resulting in failure of the grip assembly and subsequent loss of control of the helicopter.

DATES: Comments must be received by December 16, 1997.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Office of the Assistant Regional Counsel, Southwest Region, Attention: Rules Docket No. 97–SW–01–AD, 2601 Meacham Blvd., Room 663, Fort Worth, Texas 76137. Comments may be inspected at this location between 9:00 a.m. and 3:00 p.m., Monday through Friday, except Federal holidays.

The service information referenced in the proposed rule may be obtained from Robinson Helicopter Company, 2901 Airport Drive, Torrance, California 90505. This information may be examined at the FAA, Office of the Regional Counsel, Southwest Region, 2601 Meacham Blvd., Room 663, Fort Worth, Texas.

FOR FURTHER INFORMATION CONTACT: Mr. Fred Guerin, Aerospace Engineer, FAA, Los Angeles Aircraft Certification Office, Airframe Branch, 3960 Paramount Boulevard, Lakewood, California 90712, telephone (562) 627–5232, fax (562) 627–5210.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications should identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained in this notice may be changed in light of the comments received.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposed rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report summarizing each FAA-public contact concerned with the substance of this proposal will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. 97–SW–01–AD.'' The postcard will be date stamped and returned to the commenter.

Availability of NPRMs

Any person may obtain a copy of this NPRM by submitting a request to the FAA, Office of the Regional Counsel, Southwest Region, Attention: Rules Docket No. 97–SW–01–AD, 2601 Meacham Blvd., Room 663, Fort Worth, Texas 76137.

Discussion

This action proposes the adoption of a new AD that is applicable to Robinson Model R44 helicopters. The proposed AD would require removing the grip assembly, part number (P/N) A756–6 Revision N (or prior), and replacing it with an airworthy grip assembly, P/N A756–6 Revision M (or later), within 25 hours time-in-service (TIS) or 30 calendar days after the effective date of this AD, whichever occurs first. This proposal is prompted by one report of a crack in the welded corner of the grip assembly. The actions specified in this proposal are intended to prevent use of a grip assembly that may crack, which could result in failure of the grip assembly and subsequent loss of control of the helicopter.

The FAA has reviewed Robinson Helicopter Company KI–112 R44 Pilot's Grip Assembly Upgrade Kit instructions, dated December 20, 1996, which describes procedures for replacement of the grip assembly.

Since an unsafe condition has been identified that is likely to exist or develop on other Robinson Model R44 helicopters of the same type design, the proposed AD would require removing the grip assembly, P/N A756–6 Revision N (or prior), and replacing it with an airworthy grip assembly, P/N A765–6 Revision M (or later), within 25 hours TIS or 30 calendar days after the effective date of this AD, whichever occurs first. The actions are required to be accomplished in accordance with the kit instructions described previously.

The FAA estimates that 5 helicopters of U.S. registry would be affected by this proposed AD, that it would take approximately 4 work hours per helicopter to accomplish the proposed actions, and that the average labor rate is $60 per work hour. Required parts would cost approximately $576 per helicopter. Based on these figures, the total cost impact of the proposed AD on U.S. operators is estimated to be $4,080.

The regulations proposed herein would not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this proposal would not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this proposed regulation (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the draft regulatory evaluation prepared for this action is contained in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption **ADDRESSES**.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding a new airworthiness directive to read as follows:

Robinson Helicopter Company: Docket No. 97–SW–01–AD.

Applicability: Model R44 helicopters, serial numbers (S/N) 0001 through 0159, except S/N 0143, 0150, and 0156, with cyclic control pilot's grip assembly (grip assembly), part number (P/N) A756–6 Revision N or prior, installed, certificated in any category.

Note 1: This AD applies to each helicopter identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For helicopters that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must use the authority provided in paragraph (b) to request approval from the FAA. This approval may address either no action, if the current configuration eliminates the unsafe condition, or different actions necessary to address the unsafe condition described in this AD. Such a request should include an assessment of the effect of the changed configuration on the

unsafe condition addressed by this AD. In no case does the presence of any modification, alteration, or repair remove any helicopter from the applicability of this AD.

Compliance: Within 25 hours time-in-service or 30 calendar days after the effective date of this AD, whichever occurs first.

To prevent use of a grip assembly that may crack, resulting in failure of the grip assembly and subsequent loss of control of the helicopter, accomplish the following:

(a) Remove the grip assembly, P/N A756–6 Revision N (or prior), and replace it with an airworthy grip assembly, P/N A756–6 Revision M (or later), in accordance with KI–112 R44 Pilot's Grip Assembly Upgrade Kit instructions, dated December 20, 1996.

(b) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Los Angeles Aircraft Certification Office. Operators shall submit their requests through an FAA Principal Maintenance Inspector, who may concur or comment and then send it to the Manager, Los Angeles Aircraft Certification Office.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Los Angeles Aircraft Certification Office.

(c) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the helicopter to a location where the requirements of this AD can be accomplished.

Issued in Fort Worth, Texas, on October 9, 1997.

Eric Bries,

Acting Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 97–27585 Filed 10–16–97; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 96–SW–21–AD]

Airworthiness Directives; Eurocopter Deutschland GmbH (ECD) Model BO 105 C and BO 105 S Helicopters

AGENCY: Federal Aviation Administration, DOT.

ACTION: Proposed rule; withdrawal.

SUMMARY: This action withdraws a notice of proposed rulemaking (NPRM) that proposed a new airworthiness directive (AD), applicable to Eurocopter Deutschland GmbH (ECD) (Eurocopter Deutschland) Model BO 105 C and BO 105 S helicopters. That action would have required modifying the main relay box by replacing the voltage regulator; modifying the cockpit overhead panel by installing two additional switches; and performing a functional test of the new voltage regulator, generators, and new switches. Since the issuance of the NPRM, the Federal Aviation Administration (FAA) has determined that the modification proposed is only necessary for Instrument Flight Rule (IFR) configurations, and since there is no IFR FAA type-design approval for the affected models, it is unnecessary to issue an AD.

FOR FURTHER INFORMATION CONTACT: Mr. Lance Gant, Aerospace Engineer, FAA, Rotorcraft Directorate, Rotorcraft Standards Staff, 2601 Meacham Blvd., Fort Worth, Texas 76137, telephone (817) 222–5114, fax (817) 222–5961.

SUPPLEMENTARY INFORMATION: A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) to add a new airworthiness directive (AD), applicable to Eurocopter Deutschland Model BO 105 C and BO 105 S helicopters, was published in the **Federal Register** on February 13, 1997 (62 FR 6746). The proposed rule would have required modifying the main relay box 1VE; modifying the cockpit overhead panel, and performing a functional test of the new voltage regulator, generators, and new switches for the affected helicopters. That action was prompted by an in-service report of a helicopter that experienced a generator overvoltage. The proposed actions were intended to prevent failure of essential electrical equipment that could result in spatial disorientation and subsequent loss of control of the helicopter.

Since the issuance of that NPRM, the FAA has determined that the need for overvoltage protection is associated with the IFR requirement to have certain avionics available; however, there is no FAA IFR type-design approval for the affected models, therefore there is no type design model on which to issue an AD.

Upon further consideration and review of this new data, the FAA has determined that the unsafe condition no longer exists and is extremely unlikely to develop. Accordingly, the proposed rule is hereby withdrawn.

Withdrawal of this notice of proposed rulemaking constitutes only such action, and does not preclude the agency from issuing another notice in the future, nor does it commit the agency to any course of action in the future.

Since this action only withdraws a notice of proposed rulemaking, it is neither a proposed nor a final rule and therefore, is not covered under Executive Order 12866, the Regulatory Flexibility Act, or DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979).

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Withdrawal

Accordingly, the notice of proposed rulemaking, Docket No. 96–SW–21–AD, published in the **Federal Register** on February 13, 1997 (62 FR 6746), is withdrawn.

Issued in Fort Worth, Texas, on October 7, 1997.

Eric Bries,

Acting Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 97–27584 Filed 10–16–97; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 97–ASO–22]

Proposed Establishment of Class D Airspace; Hickory, NC

AGENCY: Federal Aviation Administration (FAA) DOT.

ACTION: Notice or proposed rulemaking.

SUMMARY: This proposed rule would establish Class D airspace at Hickory, NC. A non-federal control tower will open at Hickory Regional Airport, Hickory, NC, on or about October 1, 1997. Class D surface area airspace is required when the control tower is open to accommodate current Standard Instrument Approach Procedures (SIAP) and for Instrument Flight Rules (IFR) operations at the airport.

DATES: Comments must be received on or before November 17, 1997.

ADDRESSES: Send comments on the proposal in triplicate to: Federal Aviation Administration, Docket No. 97–ASO–22, Manager, Airspace Branch, ASO–520, P.O. Box 20636, Atlanta, Georgia 30320

The official docket may be examined in the Office of the Assistant Chief Counsel for Southern Region, Room 550, 1701 Columbia Avenue, College Park, Georgia 30337, telephone (404) 305–5586. An informal docket may also be examined during normal business hours at the address listed above.

FOR FURTHER INFORMATION CONTACT: Nancy B. Shelton, Airspace Branch, Air Traffic Division, Federal Administration, P.O. Box 20636, Atlanta, Georgia 30320; telephone (404) 305-5491.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental and energy-related aspects of the proposal. Communications should identify the airspace docket number and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Airspace Docket No. 97–ASO–22.'' The postcard will be date/time stamped and returned to the commenter. All communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of the comments received. All comments submitted will be available for examination in the Office of the Assistant Chief Counsel for Southern Region, Room 550, 1701 Columbia Avenue, College Park, Georgia 30337, both before and after the closing date for comments. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

Any person may obtain a copy of this Notice of Proposed Rulemaking (NPRM) by submitting a request to the Federal Aviation Administration, Manager, Airspace Branch, ASO–520, Air Traffic Division, P.O. Box 20636, Atlanta, Georgia 30320. Communications must identify the notice number of this NPRM. Persons interested in being placed on a mailing list for future NPRMs should also request a copy of Advisory Circular No. 11–2A, which describes the application procedure.

The Proposal

The FAA is considering an amendment to part 71 of the Federal Aviation Regulations (14 CFR Part 71) to establish Class D airspace at Hickory, NC. A nonfederal control tower will open at Hickory Regional Airport, Hickory, NC, on or about October 1, 1997. Class D surface area airspace is required when the control tower is open to accommodate current SIAPs and for IFR operations at the airport. Class D airspace designations are published in Paragraph 5000 of FAA Order 7400.9E, dated September 10, 1997, and effective September 16, 1997, which is incorporated by reference, in 14 CFR 71.1. The Class D airspace designation listed in this document would be published subsequently in the Order.

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore: (1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR part 71

Airspace, Incorporation by reference, Navigation (Air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, CLASS B, CLASS C, CLASS D, AND CLASS E AIRSPACE AREAS; AIRWAYS; ROUTES; AND REPORTING POINTS

1. The authority citation for Part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.9E, Airspace Designations and Reporting Points, dated September 10, 1997, and effective September 16, 1997, is amended as follows:

Paragraph 5000 Class airspace.

* * * * *

ASO NC D Hickory, NC [New]

Hickory Regional Airport, NC
(Lat. 35°44′28″N, long. 81°23′22″W)

That airspace extending upward from the surface to and including 3700 feet MSL within a 4.1-mile radius of Hickory Regional Airport. This Class D airspace is effective during the specific days and times established in advance by a Notice to Airmen. The effective days and times will thereafter be continuously published in the Airport/Facility Director.

* * * * *

Issued in College Park, Georgia, on September 9, 1997.

Nancy B. Shelton,

Maager, Air Traffic Division, Southern Region.

[FR Doc. 97–27391 Filed 10–16–97; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 97–AEA–35]

Proposed Establishment of Class E Airspace; Churchville, MD

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: This proposed rule would establish Class E Airspace at Churchville, MD. The development of new Standard Instrument Approach Procedures (SIAP) at Harford Country Airport based on the Global Positioning System (GPS) and VHF Omnidirectional Radio Range (VOR) has made this proposal necessary. Additional controlled airspace extending upward from 700 feet Above Ground Level (AGL) is needed to accommodate the SIAPs and for Instrument Flight Rules (IFR) operations to the airport. The area would be depicted on aeronautical charts for pilot reference.

DATES: Comments must be received on or before November 17, 1997.

ADDRESSES: Send comments on the proposed rule in triplicate to: Manager, Airspace Branch, AEA–520, Docket No. 97–AEA–35, F.A.A. Eastern Region, Federal Building #111, John F. Kennedy Int'l Airport, Jamaica, NY 11430. The office docket may be examined in the Office of the Assistant Chief Counsel, AEA–7, F.A.A. Eastern Region, Federal Building #111, John F. Kennedy International Airport, Jamaica, New York 11430.

An informal docket may also be examined during normal business hours in the Operations Branch, AEA–530,

F.A.A. Eastern Region, Federal Building #111, John F. Kennedy International Airport, Jamaica, NY 11430.

FOR FURTHER INFORMATION CONTACT: Mr. Francis T. Jordan, Jr., Airspace Specialist, Airspace Branch, AEA–520, F.A.A. Eastern Region, Federal Building #111, John F. Kennedy International Airport, Jamaica, New York 11430; telephone: (718) 553–4521.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify the airspace docket number and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Airspace Docket No. 97–AEA–35''. The postcard will be date/time stamped and returned to the commenter.

All communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in the light of comments received. All comments submitted will be available for examination in the Rules Docket both before and after the closing date for comments. A report summarizing each substantive public contact with the FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

Any person may obtain a copy of this Notice of Proposed Rulemaking (NPRM) by submitting a request to the Office of the Assistant Chief Counsel, AEA–7, F.A.A. Eastern Region, Federal Building #111, John F. Kennedy International Airport, Jamaica, NY 11430. Communications must identify the notice number of this NPRM. Persons interested in being placed on a mailing list for future NPRMs should also request a copy of Advisory Circular No. 11–2A, which describes the application procedure.

The Proposal

The FAA is considering an amendment to Part 71 of the Federal Aviation Regulations (14 CFR part 71) to establish Class E airspace extending upward from 700 feet AGL at Churchville, MD. A GPS RWY 10 SIAP and a VOR A SIAP have been developed for Harford County Airport. Additional controlled airspace extending upward from 700 feet AGL is needed to accommodate these SIAPs and for IFR operations at the airport. The area would be depicted on appropriate aeronautical charts. Class E airspace designations for airspace extending upward from 700 feet above the surface are published in Paragraph 6005 of FAA Order 7400.9E, dated September 10, 1997, and effective September 16, 1997, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document would be published subsequently in the Order.

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this proposed regulation—(1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 10034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that would only affect air traffic procedures and air navigation, it is certified that this proposed rule would not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—[AMENDED]

1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854; 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.9E, Airspace Designations and Reporting Points, dated September 10, 1997, and effective September 16, 1997, is amended as follows:

Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.

* * * * *

AEA MD E5 Churchville, MD [New]

Harford County Airport, MD
(Lat. 39°43′02″ N., long. 76°12′07″ W.)

That airspace extending upward from 700 feet above the surface within a 6.5-mile radius of Harford County Airport, excluding the airspace in Restricted Area R–4001 A when it is in effect, and the Aberdeen, MD, and Edgewood, MD, Class E airspace areas.

* * * * *

Issued in Jamaica, New York, on August 20, 1997.

Franklin D. Hatfield,

Manager, Air Traffic Division, Eastern Region.

[FR Doc. 97–27373 Filed 10–16–97; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 97–AEA–37]

Proposed Establishment of Class E Airspace; Ticonderoga, NY

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: This proposed rule would establish Class E Airspace at Ticonderoga, NY. The development of new Standard Instrument Approach Procedures (SIAP) at Ticonderoga Municipal Airport based on the Global Positioning System (GPS) has made this proposal necessary. Additional controlled airspace extending upward from 700 feet Above Ground Level (AGL) is needed to accommodate the SIAPs and for Instrument Flight Rules (IFR) operations to the airport. The area would be depicted on aeronautical charts for pilot reference.

DATES: Comments must be received on or before November 17, 1997.

ADDRESSES: Send comments on the proposed rule in triplicate to: Manager, Airspace Branch, AEA–520, Docket No. 97–AEA–37, F.A.A. Eastern Region, Federal Building #111, John F. Kennedy Int'l Airport, Jamaica, NY 11430. The official docket may be examined in the Office of the Assistant Chief Counsel, AEA–7, F.A.A. Eastern Region, Federal Building #111, John F. Kennedy

International Airport, Jamaica, New York 11430.

An informal docket may also be examined during normal business hours in the Airspace Branch, AEA–520, F.A.A. Eastern Region, Federal Building #111, John F. Kennedy International Airport, Jamaica, NY 11430.

FOR FURTHER INFORMATION CONTACT: Mr. Francis T. Jordan, Jr., Airspace Specialist, Airspace Branch, AEA–520, F.A.A. Eastern Region, Federal Building #111, John F. Kennedy International Airport, Jamaica, NY 11430; telephone: (718) 553–4521.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify the airspace docket number and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Airspace Docket No. 97–AEA–37''. The postcard will be date/time stamped and returned to the commenter.

All communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in the light of comment received. All comments submitted will be available for examination in the Rules Docket both before and after the closing date for comments. A report summarizing each substantive public contact with the FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

Any person may obtain a copy of this Notice of Proposed Rulemaking (NPRM) by submitting a request to the Office of the Assistant Chief Counsel, AEA–7, F.A.A. Eastern Region, Federal Building #111, John F. Kennedy International Airport, Jamaica, NY 11430. Communications must identify the notice number of this NPRM. Persons interested in being placed on a mailing list for future NPRMs should also request a copy of Advisory Circular No. 11–2A, which describes the application procedure.

The Proposal

The FAA is considering an amendment to Part 71 of the Federal Aviation Regulations (14 CFR part 71) to establish Class E airspace extending upward from 700 feet AGL at Ticonderoga, NY. A GPS RWY 2 SIAP and a GPS RWY 20 SIAP have been developed for Ticonderoga Municipal Airport. Additional controlled airspace extending upward from 700 feet AGL is needed to accommodate the SIAPs and for IFR operations at the airport. The area would be depicted on appropriate aeronautical charts. Class E airspace designations for airspace extending upward from 700 feet above the surface are published in Paragraph 6005 of FAA Order 7400.9E, dated September 10, 1997, and effective September 16, 1997, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document would be published subsequently in the Order.

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this proposed regulation—(1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that would only affect air traffic procedures and air navigation, it is certified that this proposed rule would not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—[AMENDED]

1. The authority citation for Part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854; 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.9E, dated September 10, 1997, and effective September 16, 1997, is amended as follows:

Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.

* * * * *

AEA NY E5 Ticonderoga, NY [New]

Ticonderoga Municipal Airport, NY
(Lat. 43° 52′ 37″N., long. 73° 24′ 47″W.)

That airspace extending upward from 700 feet above the surface within an 11-mile radius of Ticondergoa Municipal Airport, excluding the portion that coincides with the Rutland, VT, Class E airspace area.

* * * * *

Issued in Jamaica, New York, on August 20, 1997.

Franklin D. Hatfield,

Manager, Air Traffic Division, Eastern Region.

[FR Doc. 97–27372 Filed 10–16–97; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 97–AEA–26]

Proposed Amendment to Class E Airspace; Wellsboro, PA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: This proposed rule would amend the Class E airspace area at Wellsboro, PA. The development of a new Standard Instrument Approach Procedure (SIAP) based on the Global Positioning System (GPS), and an amendment to an existing SIAP, at Grand Canyon State Airport has made this proposal necessary. Additional controlled airspace extending upward from 700 feet Above Ground Level (AGL) is needed to accommodate the SIAPs and for Instrument Flight Rules (IFR) operations at the airport. A correction is also being proposed in the geographic position coordinates of Grand Canyon State Airport and a correction to the airspace use time restrictions.

DATES: Comments must be received on or before November 17, 1997.

ADDRESSES: Send comments on the proposal in triplicate to: Manager, Airspace Branch, AEA–520, Docket No. 97–AEA–26, F.A.A. Eastern Region,

Federal Building #111, John F. Kennedy Int'l Airport, Jamaica, NY 11430.

The official docket may be examined in the Office of the Assistant Chief Counsel, AEA–7, F.A.A. Eastern Region, Federal Building #111, John F. Kennedy International Airport, Jamaica, New York 11430.

An informal docket may also be examined during normal business hours in the Airspace Branch, AEA–520, F.A.A. Eastern Region, Federal Building #111, John F. Kennedy International Airport, Jamaica, NY 11430.

FOR FURTHER INFORMATION CONTACT: Mr. Francis T. Jordan, Jr., Airspace Specialist, Airspace Branch, AEA–520 F.A.A. Eastern Region, Federal Building #111, John F. Kennedy International Airport, Jamaica, New York 11430; telephone: (718) 553–4521.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, economic, environmental, and energy-related aspects of the proposal. Communications should identify the airspace docket number and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Airspace Docket No. 97–AEA–26.'' The postcard will be date/time stamped and returned to the commenter. All communications received on or before the closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of comments received. All comments submitted will be available for examination in the Rules Docket both before and after the closing date for comments. A report summarizing each substantive public contact with the FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

Any person may obtain a copy of this Notice of Proposed Rulemaking (NPRM) by submitting a request to the Office of the Assistant Chief Counsel, AEA–7, F.A.A. Eastern Region, Federal Building #111, John F. Kennedy International Airport, Jamaica, NY 11430. Communications must identify the notice number of this NPRM. Persons interested in being placed on a mailing list for future NPRMs should also request a copy of Advisory Circular No. 11–2A, which describes the application procedure.

The Proposal

The FAA is considering an amendment to Part 71 of the Federal Aviation Regulations (14 CFR Part 71) to amend the Class E airspace area at Wellsboro, PA. A GPS RWY 28 SIAP has been developed, and the VOR/GPS A SIAP has been amended, for the Grand Canyon State Airport. Additional controlled airspace extending upward from 700 feet AGL is needed to accommodate the SIAPs and for IFR operations at the airport. The geographic position coordinates of the airport have been revised and the airspace use time restrictions are deleted. Class E airspace designations for airspace areas extending upward from 700 feet or more above the surface are published in Paragraph 6005 of FAA Order 7400.9E, dated September 10, 1997, and effective September 16, 1997, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document would be published subsequently in the Order.

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this proposed regulation—(1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that would only affect air traffic procedures and air navigation, it is certified that this proposed rule would not have significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporated by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR Part 71 as follows:

PART 71—[AMENDED]

1. The authority citation for Part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854; 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.9E, dated September 10, 1997, and effective September 16, 1997, is amended as follows:

Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.

* * * * *

AEA PA E5 Wellsboro, PA [Revised]

Grand Canyon State Airport, Wellsboro, PA
(Lat. 41°43′40″N., long. 77°23′47″W.)
Stonyfork VORTAC
(Lat. 41°41′43″N., long. 77°25′12″W.)

That airspace extending upward from 700 feet above the surface within a 6.5-mile radius of Grand Canyon State Airport and within 4 miles each side of the 208° bearing from the Stonyfork VORTAC extending from the 6.5-mile radius to 7 miles southwest of the VORTAC.

* * * * *

Issued in Jamaica, New York, on August 20, 1997.

Franklin D. Hatfield,

Manager, Air Traffic Division, Eastern Region.

[FR Doc. 97–27371 Filed 10–16–97; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 97–AEA–27]

Proposed Amendment to Class E Airspace; Pineville, WV

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: This proposed rule would amend the Class E airspace area at Pineville, WV. The development of new Standard Instrument Approach Procedures (SIAP) based on the Global Positioning System (GPS) and VHF Omnidirectional Radio Range (VOR) at Kee Field Airport has made this proposal necessary. Additional controlled airspace extending upward from 700 feet Above Ground Level (AGL) is needed to accommodate the SIAPs and for Instrument Flight Rules (IFR) operations at the airport.

DATES: Comments must be received on or before November 17, 1997.

ADDRESSES: Send comments on the proposal in triplicate to: Manager, Airspace Branch, AEA–520, Docket No. 97–AEA–27, F.A.A. Eastern Region, Federal Building #111, John F. Kennedy Int'l Airport, Jamaica, NY 11430.

The official docket may be examined in the Office of the Assistant Chief Counsel, AEA–7, F.A.A. Eastern Region, Federal Building #111, John F. Kennedy International Airport, Jamaica, NY 11430.

An informal docket may also be examined during normal business hours in the Airspace Branch, AEA–520, F.A.A. Eastern Region, Federal Building #111, John F. Kennedy International Airport, Jamaica, NY 11430.

FOR FURTHER INFORMATION CONTACT: Mr. Francis T. Jordan, Jr., Airspace Specialist, Airspace Branch, AEA–520 F.A.A. Eastern Region, Federal Building #111, John F. Kennedy International Airport, Jamaica, New York 11430; telephone (718) 553–4521.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, economic, environmental, and energy-related aspects of the proposal. Communications should identify the airspace docket number and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Airspace Docket No. 97–AEA–27''. The postcard will be date/time stamped and returned to the commenter. All communications received on or before the closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of comments received. All comments submitted will be available for examination in the Rules Docket both before and after the closing date for comments. A report summarizing each substantive public contact with the FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

Any person may obtain a copy of this Notice of Proposed Rulemaking (NPRM) by submitting a request to the Office of the Assistant Chief Counsel, AEA–7, F.A.A. Eastern Region, Federal Building #111, John F. Kennedy International Airport, Jamaica, NY 11430. Communications must identify the notice number of this NPRM. Persons interested in being placed on a mailing list for future NPRMs should also request a copy of Advisory Circular No. 11–2A, which describes the application procedure.

The Proposal

The FAA is considering an amendment to Part 71 of the Federal Aviation Regulations (14 CFR Part 71) to amend the Class E airspace area at Pineville, WV. A GPS RWY 25 SIAP, GPS RWY 7 SIAP, and a VOR RWY 25 SIAP have been developed for the Kee Field Airport. Additional controlled airspace extending upward from 700 feet AGL is needed to accommodate the SIAPs and for IFR operations at the airport. Class E airspace designations for airspace areas extending upward from 700 feet or more above the surface are published in Paragraph 6005 of FAA Order 7400.9E, dated September 10, 1997, and effective September 16, 1997, which is incorporated by reference in 14 CFR 71.1 The Class E airspace designation listed in this document would be published subsequently in the Order.

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this proposed regulation—(1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that would only affect air traffic procedures and air navigation, it is certified that this proposed rule would not have significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR Part 71 as follows:

PART 71—[AMENDED]

1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854; 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.9E, dated September 10, 1997, and effective September 16, 1997, is amended as follows:

Paragraph 6005 Class E Airspace areas extending upward from 700 feet or more above the surface of the earth.

* * * * *

AEA WV E5 Pineville, WV [Revised]

Kee Field Airport, Pineville, WV
(Lat. 37°36′01″ N., long. 81°33′33″ W.)

That airspace extending upward from 700 feet above the surface within a 7.2-mile radius of Kee Field Airport and within 4 miles each side of the 249° bearing from the Kee Field Airport extending from the 7.2-mile radius to 10 miles southwest of the airport and within 4 miles south and 5.7 miles north of the 062° bearing from the Kee Field Airport extending from the 7.2 mile radius to 21 miles northeast of the airport excluding that portion that coincides with the Beckley, WV Class E airspace area.

* * * * *

Issued in Jamaica, New York, on August 20, 1997.

Franklin D. Hatfield,

Manager, Air Traffic Division, Eastern Region.

[FR Doc. 97–27370 Filed 10–16–97; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 97–ASO–15]

Proposed Amendment of Class E Airspace; Birmingham, AL

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: This proposed rule would amend Class E airspace at Birmingham, AL. A Global Positioning System (GPS) Runway (RWY) 23 Standard Instrument Approach Procedure (SIAP) has been developed for Birmingham International Airport. As a result, additional controlled airspace extending upward from 700 feet Above Ground Level (AGL) is needed to accommodate the

SIAP and for Instrument Flight Rules (IFR) operations at Birmingham International Airport.

DATES: Comments must be received on or before November 17, 1997.

ADDRESSES: Send comments on the proposal in triplicate to: Federal Aviation Administration, Docket No. 97–ASO–15, Manager, Airspace Branch, ASO–520, P.O. Box 20636, Atlanta, Georgia 30320.

The official docket may be examined in the Office of the Assistant Chief Counsel for Southern Region, Room 550, 1701 Columbia Avenue, College Park, Georgia 30337, telephone (404) 305–5586.

FOR FURTHER INFORMATION CONTACT: Nancy B. Shelton, Airspace Branch, Air Traffic Division, Federal Aviation Administration, P.O. Box 20636, Atlanta, Georgia 30320; telephone (404) 305–5491.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify the airspace docket number and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Airspace Docket No. 97–ASO–15.'' The postcard will be date/time stamped and returned to the commenter. All communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of the comments received. All comments submitted will be available for examination in the Office of the Assistant Chief Counsel for Southern Region, Room 550, 1701 Columbia Avenue, College Park, Georgia 30337, both before and after the closing date for comments. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availaiblity of NPRMs

Any person may obtain a copy of this Notice of Proposed Rulemaking (NPRM) by submitting a request to the Federal Aviation Administration, Manager, Airspace Branch, ASO–520, Air Traffic Division, P.O. Box 20636, Atlanta, Georgia 30320. Communications must identify the notice number of this NPRM. Persons interested in being placed on a mailing list for future NPRMs should also request a copy of Advisory Circular No. 11–2A, which describes the application procedure.

The Proposal

The FAA is considering an amendment to part 71 of the Federal Aviation Regulations (14 CFR part 71) to amend Class E airspace at Birmingham, AL. A GPS RWY 23 SIAP has been developed for Birmingham International Airport. Additional controlled airspace extending upward from 700 feet AGL is needed to accommodate the SIAP and for IFR operations at Birmingham International Airport. Class E airspace designations for airspace areas extending upward from 700 feet or more above the surface of the earth are published in Paragraph 6005 of FAA Order 7400.9E, dated September 10, 1997, and effective September 16, 1997, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document would be published subsequently in the Order.

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore, (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, CLASS B, CLASS C, CLASS D, AND CLASS E AIRSPACE AREAS; AIRWAYS; ROUTES; AND REPORTING POINTS

1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.9E, Airspace Designations and Reporting Points, dated September 10, 1997, and effective September 16, 1997, is amended as follows:

Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.

* * * * *

ASO AL E5 Birmingham, AL [Revised]

Birmingham International Airport, AL
(lat. 33°33′47″N, long. 86°45′13″W)

That airspace extending upward from 700 feet above the surface within a 10-mile radius of Birmingham International Airport.

* * * * *

Issued in College Park, Georgia, on September 4, 1997.

Nancy B. Shelton,

Acting Manager, Air Traffic Division Southern Region.

[FR Doc. 97–27369 Filed 10–16–97; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 97–AEA–39]

Proposed Amendment to Class E Airspace; Syracuse, NY

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: This proposed rule would amend the Class E airspace area at Syracuse, NY. The development of new Standard Instrument Approach Procedures (SIAP) based on the Global Positioning System (GPS) at Syracuse Hancock International Airport has made this proposal necessary. Additional controlled airspace extending upward from 700 feet Above Ground Level (AGL) is needed to accommodate the

SIAPs and for Instrument Flight Rules (IFR) operations at the airport.

DATES: Comments must be received on or before November 17, 1997.

ADDRESSES: Send comments on the proposal in triplicate to: Manager, Airspace Branch, AEA–520, Docket No. 97–AEA–39, F.A.A. Eastern Region, Federal Building #111, John F. Kennedy Int'l Airport, Jamaica, NY 11430.

The official docket may be examined in the Office of the Assistant Chief Counsel, AEA–7, F.A.A. Eastern Region, Federal Building #111, John F. Kennedy International Airport, Jamaica, NY 11430.

An informal docket may also be examined during normal business hours in the Airspace Branch, AEA–520, F.A.A. Eastern Region, Federal Building #111, John F. Kennedy International Airport, Jamaica, NY 11430.

FOR FURTHER INFORMATION CONTACT: Mr. Francis T. Jordan, Jr., Airspace Specialist, Airspace Branch, AEA–520, F.A.A. Eastern Region, Federal Building #111, John F. Kennedy International Airport, Jamaica, NY 11430; telephone: (718) 553–4521.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, economic, environmental, and energy-related aspects of the proposal. Communications should identify the airspace docket number and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Airspace Docket No. 97–AEA–39.'' The postcard will be date/time stamped and returned to the commenter. All communications received on or before the closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of comments received. All comments submitted will be available for examination in the Rules Docket both before and after the closing date for comments. A report summarizing each substantive public contact with the FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

Any person may obtain a copy of this Notice of Proposed Rulemaking (NPRM) by submitting a request to the Office of the Assistant Chief Counsel, AEA–7, F.A.A. Eastern Region, Federal Building #111, John F. Kennedy International Airport, Jamaica, NY 11430. Communications must identify the notice number of this NPRM. Persons interested in being placed on a mailing list for future NPRMs should also request a copy of Advisory Circular No. 11–2A, which describes the application procedure.

The Proposal

The FAA is considering an amendment to Part 71 of the Federal Aviation Regulations (14 CFR Part 71) to amend the Class E airspace area at Syracuse, NY. A GPS runway (RWY) 10 SIAP, GPS RWY 14 SIAP, GPS RWY 28 SIAP, and a GPS RWY 32 SIAP have been developed for Syracuse Hancock International Airport. Additional controlled airspace extending upward from 700 feet AGL is needed to accommodate the SIAPs and for IFR operations at the airport. Class E airspace designations for airspace areas extending upward from 700 feet or more above the surface are published in Paragraph 6005 of FAA Order 7400.9E, dated September 10, 1997, and effective September 16, 1997, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document would be published subsequently in the Order.

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this proposed regulation—(1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that would only affect air traffic procedures and air navigation, it is certified that this proposed rule would not have significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—[AMENDED]

1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854; 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.9E, airspace designations and reporting points, dated September 10, 1997, and effective September 16, 1997, is amended as follows:

Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.

* * * * *

AEA NY E5 Syracuse, NY [Revised]

Syracuse Hancock International Airport, Syracuse, NY
(Lat. 43°06′40″ N., long. 76°06′23″ W.)

That airspace extending upward from 700 feet above the surface within a 14-mile radius of Syracuse Hancock International Airport and within a 20-mile radius of the airport extending clockwise from a 245° bearing to a 305° bearing from the airport, excluding that portion that coincides with the Fulton, NY, Durhamville, NY, and Skaneateles, NY Class E airspace areas.

* * * * *

Issued in Jamaica, New York, on September 5, 1997.

Franklin D. Hatfield,

Manager, Air Traffic Division, Eastern Region.

[FR Doc. 97–27368 Filed 10–16–97; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 97–AEA–40]

Proposed Amendment to Class E Airspace; Lewisburg, WV

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: This proposed rule would amend the Class E airspace area at Lewisburg, WV. The development of new Standard Instrument Approach Procedures (SIAP) based on a VHF Omnidirectional Radio Rand (VOR) at Greenbrier Valley Airport has made this

proposal necessary. Additional controlled airspace extending upward from 700 feet Above Ground Level (AGL) is needed to accommodate the SIAPs and for Instrument Flight Rules (IFR) operations at the airport.

DATES: Comments must be received on or before November 17, 1997.

ADDRESSES: Send comments on the proposal in triplicate to: Manager, Airspace Branch, AEA–520, Docket No. 97–AEA–40, F.A.A. Eastern Region, Federal Building #111, John F. Kennedy Int'l Airport, Jamaica, NY 11430.

The official docket may be examined in the Office of the Assistant Chief Counsel, AEA–7, F.A.A. Eastern Region, Federal Building #111, John F. Kennedy International Airport, Jamaica, New York 11430.

An informal docket may also be examined during normal business hours in the Airspace Branch, AEA–520, F.A.A. Eastern Region, Federal Building #111, John F. Kennedy International Airport, Jamaica, NY 11430.

FOR FURTHER INFORMATION CONTACT: Mr. Francis T. Jordan, Jr., Airspace Specialist, Airspace Branch, AEA–520, F.A.A. Eastern Region, Federal Building #111, John F. Kennedy International Airport, Jamaica, New York 11430; telephone: (718) 553–4521.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested parties are invited to participate in this proposed rulemaking such written data, views, or arguments as they may desire. Comments that provide the factual basis supporting the views, and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, economic, environmental, and energy-related aspects of the proposal. Communications should identify the airspace docket number and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Airspace Docket No. 97–AEA–40.'' The post card will be date/time stamped and returned to the commenter. All communications received on or before the closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of comments received. All comments submitted will be available for examination in the Rules Docket both before and after the closing date for comments. A report summarizing each substantive public contact with the FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

Any person may obtain a copy of this Notice of Proposed Rulemaking (NPRM) by submitting a request to the Office of the Assistant Chief Counsel, AEA–7, F.A.A. Eastern Region, Federal Building #111, John F. Kennedy International Airport, Jamaica, NY 11430. Communications must identify the notice number of this NPRM. Persons interested in being placed on a mailing list for future NPRMs should also request a copy of Advisory Circular No. 11–2A, which describes the application procedure.

The Proposal

The FAA is considering an amendment to Part 71 of the Federal Aviation Regulations (14 CFR Part 71) to amend the Class E airspace area at Lewisburg, WV. A VOR runway (RWY) 4 SIAP and a VOR RWY 22 SIAP have been developed for the Greenbrier Valley Airport. Additional controlled airspace extending upward from 700 feet AGL is needed to accommodate the SIAPs and for IFR operations at the airport. Class E airspace designations for airspace areas extending upward from 700 feet or more above the surface are published in Paragraph 6005 of FAA Order 7400.9E, dated September 10, 1997, and effective September 16, 1997, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document would be published subsequently in the Order.

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this proposed regulation—(1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that would only affect air traffic procedures and air navigation, it is certified that this proposed rule would not have significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—[AMENDED]

1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 10120; E.O. 10854; 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.9E, Airspace Designations and Reporting Points, dated September 10, 1997, and effective September 16, 1997 is amended as follows:

Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.

* * * * *

AEA WV E5 Lewisburg, WV [Revised]

Greenbrier Valley Airport, Lewisburg, WV
(Lat. 37°51′40″ N., long. 80°23′58″ W.)
BUSHI NDB (LOM)
(Lat. 37°46′56″ N., long. 80°28′06″ W.)

That airspace extending upward from 700 feet above the surface within a 12-mile radius of Greenbrier Valley Airport and within 4.4 miles each side of the 217° bearing from the BUSHI NDB (LOM) extending from the 12-mile radius to 10 miles southwest of the NDB (LOM).

* * * * *

Issued in Jamaica, New York, on September 5, 1997.

Franklin D. Hatfield,

Manager, Air Traffic Division, Eastern Region.

[FR Doc. 97–27367 Filed 10–16–97; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 97–AWP–29]

Proposed Amendment of Class E Airspace; Yuma, AZ

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: The proposed rule would amend the Class E airspace area at Yuma, AZ. The establishment of a Global Positioning System (GPS)

Standard Instrument Approach Procedure (SIAP) to Runway (RWY) 17 and a GPS SIAP to RWY 21 R at Yuma Marine Corp Air Station (MCAS)-Yuma International Airport has made this proposal necessary. Additional controlled airspace areas extending upward from the surface, and from 700 feet above ground level (AGL) are needed to contain aircraft executing the approach. The intended effect of this proposal would be to provide adequate controlled airspace for Instrument Flight Rules (IFR) operations at Yuma MCAS-Yuma International Airport, Yuma, AZ.

DATES: Comments must be received on or before November 17, 1997.

ADDRESSES: Send comments on the proposal in triplicate to: Federal Aviation Administration, Attn: Manager, Airspace Branch, AWP–520, Docket No. 97–AWP–29, Air Traffic Division, 15000 Aviation Boulevard, Lawndale, California 90261. The official docket may be examined in the Office of the Assistant Chief Counsel, Western Pacific Region, Federal Aviation Administration, Room 6007, 15000 Aviation Boulevard, Lawndale, California 90261.

An informal docket may also be examined during normal business hours at the Office of the Manager, Airspace Branch, Air Traffic Division at the above address.

FOR FURTHER INFORMATION CONTACT: Larry Tonish, Airspace Specialist, Airspace Branch, AWP–520, Air Traffic Division, Western-Pacific Region, Federal Aviation Administration, 15000 Aviation Boulevard, Lawndale, California 90261, telephone (210) 725–6531.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify the airspace docket number and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with the comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Airspace Docket No. 97–AWP–29.'' The postcard will be date/time stamped and returned to the commenter. All communications received on or before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of comments received. All comments submitted will be available for examination in the Airspace Branch, Air Traffic Division, 15000 Aviation Boulevard, Lawndale, California 90261, both before and after the closing date for comments. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRM

Any person may obtain a copy of this Notice of Proposed Rulemaking (NPRM) by submitting a request to the Federal Aviation Administration, Airspace Branch, 15000 Aviation Boulevard, Lawndale, California 90261. Communications must identify the notice number of this NPRM. Persons interested in being placed on mailing list for future NPRM's should also request a copy of Advisory Circular No. 11–2A, which describes the application procedures.

The Proposal

The FAA is considering an amendment to part 71 of the Federal Aviation Regulations (14 CFR part 71) to amend the Class E airspace area at Yuma, AZ. The establishment of a GPS RWY 17 SIAP and GPS RWY 21R SIAP at Yuma MCAS-Yuma International Airport has made this proposal necessary. Additional controlled airspace areas extending upward from the surface, and from 700 feet AGL are needed to contain aircraft executing the approach. The intended effect of this proposal would be to provide adequate controlled airspace for aircraft executing the GPS RWY 17 SIAP and GPS RWY 21R SIAP at Yuma MCAS-Yuma International Airport, Yuma, AZ. Class E airspace designations for airspace areas designated as an extension to a Class D or Class E surface area and for airspace areas extending upward from 700 feet or move above the surface of the earth are published in Paragraphs 6004 and 6005 of FAA Order 7400.9E, dated September 10, 1997, and effective September 16, 1997, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document would be published subsequently in the Order.

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. There, this proposed regulation—(1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this proposed rule would not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—[AMENDED]

1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9E, Airspace Designations and Reporting Points, dated September 10, 1997, and effective September 16, 1997, is amended as follows:

Paragraph 6004 Class E airspace areas designated as an extension to a Class D or Class E surface area

* * * * *

AWP AZ E4 Yuma, AZ [Revised]

Yuma MCAS-Yuma International Airport, AZ
(lat. 32°39′23″ N, long. 114°36′22″ W)
Bard VORTAC
(lat. 32°46′05″ N, long. 114°63′10″ W)

That airspace extending upward from the surface within 1.8 miles either side of the Bard VORTAC 181° radial extending from the Bard VORTAC to the 5.2-mile radius of the Yuma MCAS-Yuma International Airport and within that airspace bounded by a line beginning at lat. 32°44′30″ N, long. 114°33′30″ W; to lat. 32°50′00″ N, long. 114°31′00″ W; to lat. 32°49′00″ N, long. 114°27′00″ W; to lat. 32°41′00″ N, long. 114°30′00″ W, thence counterclockwise via the 5.2-miles radius of the Yuma MCAS-

Yuma International Airport to the point of beginning.

* * * * *

Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.

* * * * *

AWP AZ E5 Yuma, AZ [Revised]

Yuma MCAS-Yuma International Airport, AZ
(lat. 32°39′23″ N, long. 114°36′22″ W)

That airspace extending upward from 700 feet above the surface beginning at lat. 32°41′00″ N, long. 114°25′09″ W, thence clockwise via the 9.6-mile radius of Yuma MCAS-Yuma International Airport to lat. 32°29′58″ N, long. 114°34′09″ W; to lat. 32°28′00″ N, long. 114°34′33″W; to lat. 32°28′00″ N, long. 114°38′43″ W; to lat. 32°29′58″ N, long. 114°38′31″ W, thence clockwise via the 9.6-mile radius of the Yuma MCAS-Yuma International Airport excluding that portion outside of the United States to lat. 32°47′44″ N; long. 114°42′03″ W; to lat. 33°08′00″ N, long. 114°55′00″W; to lat. 33°08′00″ N, long. 114°30′00″ W; to lat. 32°57′30″ N, long. 114°30′00″ W; to lat. 32°57′30″ N, long. 114°15′03″ W; to lat. 32°41′00″ N, long. 114°15′03″ W, thence to the point of beginning. That airspace extending upward from 1,200 feet above the surface bounded by an area starting at a point lat. 33°02′00″ N, long. 114°51′03″ W; to lat. 33°05′30″ N, long. 114°24′33″ W; to lat. 32°23′00″ N, long. 114°24′33″ W; to lat. 32°29′30″ N, long. 114°46′03″ W, thence to the point of beginning excluding that portion outside the United States. That airspace extending upward from 4,000 feet MSL, bounded by an area at lat. 33°22′30″ N, long 114°47′33″ W; to lat. 33°08′00″ N, long. 114°45′00″ W; to lat. 33°08′00″ N, long. 114°55′00″ W; to lat. 33°00′00″ N, long. 114°50′00″ W; to lat. 32°49′33″N, long. 114°49′08″ W; to lat. 32°49′12″ N, long. 115°15′16″ W; to lat. 32°52′23″ N, long. 115°15′24″ W; to lat. 32°56′20″ N, long. 115°15′03″ W; to lat. 33°04′00″ N, long. 114°56′03″ W; to lat. 33°24′00″ N, long. 114°53′03″ W, thence to the point of beginning. That airspace extending upward from 9,000 feet MSL bounded on the west by the eastern edge of V–135, on the south by lat. 33°08′00″ W, on the north by the arc of the 15.8-mile radius south of the Blythe Airport, and on the east by the eastern edge of R–2306B and R–2306A, thence to the point of beginning.

* * * * *

Issued in Los Angeles, California, on August 14, 1997.

Kathleen Y. Brown,

Acting Manager, Air Traffic Division, Western-Pacific Region.

[FR Doc. 97–27375 Filed 10–16–97; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 97–AEA–36]

Proposed Establishment of Class E Airspace; Towanda, PA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: This proposed rule would establish Class E Airspace at Towanda, PA. The development of a new Standard Instrument Approach Procedure (SIAP) at Bradford County Airport based on the Global Positioning System (GPS) has made this proposal necessary. Additional controlled airspace extending upward from 700 feet Above Ground Level (AGL) is needed to accommodate the SIAP and for Instrument Flight Rules (IFR) operations to the airport. The area would be depicted on aeronautical charts for pilot reference.

DATES: Comments must be received on or before November 17, 1997.

ADDRESSES: Send comments on the proposed rule in triplicate to: Manager, Airspace Branch, AEA–520, Docket No. 97–AEA–36, F.A.A. Eastern Region, Federal Building #111, John F. Kennedy Int'l Airport, Jamaica, NY 11430. The official docket may be examined in the Office of the Assistant Chief Counsel, AEA–7, F.A.A. Eastern Region, Federal Building #111, John F. Kennedy International Airport, Jamaica, New York 11430.

An informal docket may also be examined during normal business hours in the Airspace Branch, AEA–520, F.A.A. Eastern Region, Federal Building #111, John F. Kennedy International Airport, Jamaica, NY 11430.

FOR FURTHER INFORMATION CONTACT: Mr. Francis T. Jordan, Jr., Airspace Specialist, Airspace Branch, AEA–520, F.A.A. Eastern Region, Federal Building #111, John F. Kennedy International Airport, Jamaica, NY 11430; telephone: (718) 553–4521.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify the airspace docket number and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Airspace Docket No. 97–AEA–36''. The postcard will be date/time stamped and returned to the commenter.

All communications received on or before the specified closing date for comments will be considered before taking action on the proposed rule. The proposals contained in this notice may be changed in the light of comments received. All comments submitted will be available for examination in the Rules Docket both before and after the closing date for comments. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

Any person may obtain a copy of this Notice of Proposed Rulemaking (NPRM) by submitting a request to the Office of the Assistant Chief Counsel, AEA–7, F.A.A. Eastern Region, Federal Building #111, John F. Kennedy International Airport, Jamaica, NY 11430. Communications must identify the notice number of this NPRM. Persons interested in being placed on a mailing list for future NPRMs should also request a copy of Advisory Circular No. 11–2A, which describes the application procedure.

The Proposal

The FAA is considering an amendment to Part 71 of the Federal Aviation Regulations (14 CFR part 71) to establish Class E airspace extending upward from 700 feet AGL at Towanda, PA. A GPS RWY 23 SIAP has been developed for Bradford County Airport. Additional controlled airspace extending upward from 700 feet AGL is needed to accommodate this SIAP and for IFR operations at the airport. The area would be depicted on appropriate aeronautical charts. Class E airspace designations for airspace extending upward from 700 feet above the surface are published in Paragraph 6005 of FAA Order 7400.9 E, dated September 10, 1997 and effective September 16, 1997, which is incorporated by reference in 14 CFR 71.1. The Class E airspace

designation listed in this document would be published subsequently in the Order.

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this proposed regulation—(1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that would only affect air traffic procedures and air navigation, it is certified that this proposed rule would not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—[AMENDED]

1. The authority citation for Part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854; 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9E, Airspace Designations and Reporting Points, dated September 10, 1997, and effective September 16, 1997 is amended as follows:

Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.

* * * * *

AEA PA E5 Towanda, PA [New]

Bradford County Airport, PA
(Lat. 41° 44′36″N., long. 76° 26′40″W.)

That airspace extending upward from 700 feet above the surface within a 6-mile radius of Bradford County Airport and within 4 miles each side of the 035° bearing from the Bradford County Airport extending from the 6-mile radius to 11 miles northeast of the airport.

* * * * *

Issued in Jamaica, New York, on September 16, 1997.

Franklin D. Hatfield,

Manager, Air Traffic Division, Eastern Region.

[FR Doc. 97–27388 Filed 10–16–97; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 97–AGL–49]

Proposed Modification of Class E Airspace; Osceola, WI

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: This proposed rule would modify Class E airspace at Osceola, WI. A Global Position System (GPS) Standard Instrument Approach Procedure (SIAP) to Runway (RWY) 28 and a Nondirectional Beacon (NDB) SIAP to RWY 28 have been developed for L.O. Simenstad Municipal Airport. Controlled airspace extending upward from 700 to 1200 feet above ground level (AGL) is needed to contain aircraft executing these approaches. This proposal would increase the radius of the existing controlled airspace. The intended effect of this proposal is to provide segregation of aircraft using instrument approach procedures in instrument conditions from other aircraft operating in visual weather conditions.

DATES: Comments must be received on or before November 17, 1997.

ADDRESSES: Send comments on the proposal in triplicate to: Federal Aviation Administration, Office of the Assistant Chief Counsel, AGL–7, Rules Docket No. 97–AGL–49, 2300 East Devon Avenue, Des Plaines, Illinois 60018.

The official docket may be examined in the Office of the Assistant Chief Counsel, Federal Aviation Administration, 2300 East Devon Avenue, Des Plaines, Illinois. An informal docket may also be examined during normal business hours at the Air Traffic Division, Operations Branch, Federal Aviation Administration, 2300 East Devon Avenue, Des Plaines, Illinois.

FOR FURTHER INFORMATION CONTACT: Michelle M. Behm, Air Traffic Division, Airspace Branch, AGL–520, Federal Aviation Administration, 2300 East Devon Avenue, Des Plaines, Illinois 60018, telephone (847) 294–7568.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify the airspace docket number and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Airspace Docket No. 97–AGL–49.'' The postcard will be date/time stamped and returned to the commenter. All communications received on or before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of comments received. All comments submitted will be available for examination in the Rules Docket, FAA, Great Lakes Region, Office of the Assistant Chief Counsel, 2300 East Devon Avenue, Des Plaines, Illinois, both before and after the closing date for comments. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRM's

Any person may obtain a copy of this Notice of Proposed Rulemaking (NPRM) by submitting a request to the Federal Aviation Administration, Office of Public Affairs, Attention: Public Inquiry Center, APA–230, 800 Independence Avenue, S.W., Washington, DC 20591, or by calling (202) 267–3484. Communications must identify the notice number of this NPRM. Persons interested in being placed on a mailing list for future NPRM's should also request a copy of Advisory Circular No. 11–2A, which describes the application procedure.

The Proposal

The FAA is considering an amendment to part 71 of the Federal Aviation Regulations (14 CFR part 71) to modify Class E airspace at Osceola, WI. This modification would accommodate

aircraft executing the GPS RWY 28 SIAP and the NDB RWY 28 SIAP at L.O. Simenstad Municipal Airport by increasing the radius of the existing controlled airspace. Controlled airspace extending upward from 700 to 1200 feet AGL is needed to contain aircraft executing these approaches. The intended effect of this action is to provide segregation of aircraft using instrument approach procedures in instrument conditions from other aircraft operating in visual weather conditions. The area would be depicted on appropriate aeronautical charts. Class E airspace designations for airspace areas extending upward from 700 feet or more above the surface of the earth are published in paragraph 6005 of FAA Order 7400.9E, dated September 10, 1997, and effective September 16, 1997, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document would be published subsequently in the Order.

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore this proposed regulation—(1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this proposed rule will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend part 71 of the Federal Aviation Regulations (14 CFR part 71) as follows:

PART 71—[AMENDED]

1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9E, Airspace Designations and Reporting Points, dated September 10, 1997, and effective September 16, 1997, is amended as follows:

Paragraph 6005 The Class E airspace areas extending upward from 700 feet or more above the surface of the earth.

* * * * *

AGL WI E5 Osceola, WI [Revised]

L.O. Simenstad Municipal Airport, WI
(Lat. 48°18′31″ N, long. 92°41′24″ W)

That airspace extending upward from 700 feet above the surface within a 6.4-mile radius of the L.O. Simenstad Municipal Airport and within 2.5 miles each side of the 113° bearing from the airport extending from the 6.4-mile radius to 7 miles southeast of the airport.

* * * * *

Issued in Des Plaines, Illinois on September 15, 1997.

Maureen Woods,

Manager, Air Traffic Division.

[FR Doc. 97–27389 Filed 10–16–97; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 97–AGL–46]

Proposed Modification of Class E Airspace; London, OH

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: This proposed rule would modify Class E airspace at London, OH. A Global Positioning System (GPS) Standard Instrument Approach Procedure (SIAP) to Runway (RWY) 08 has been developed for Madison County Airport. Controlled airspace extending upward from 700 to 1200 feet above ground level (AGL) is needed to contain aircraft executing the approach. This proposal would increase the radius and enlarge the west extension of the existing controlled airspace. The intended effect of this proposal is to provide segregation of aircraft using instrument approach procedures in instrument conditions from other aircraft operating in visual weather conditions.

DATES: Comments must be received on or before November 17, 1997.

ADDRESSES: Send comments on the proposal in triplicate to: Federal Aviation Administration, Office of the Assistant Chief Counsel, AGL–7, Rules Docket No. 97–AGL–46, 2300 East Devon Avenue, Des Plaines, Illinois 60018.

The official docket may be examined in the Office of the Assistant Chief Counsel, Federal Aviation Administration, 2300 East Devon Avenue, Des Plaines, Illinois. An informal docket may also be examined during normal business hours at the Air Traffic Division, Operations Branch, Federal Aviation Administration, 2300 East Devon Avenue, Des Plaines, Illinois

FOR FURTHER INFORMATION CONTACT:

Michelle M. Behm, Air Traffic Division, Airspace Branch, AGL–520, Federal Aviation Administration, 2300 East Devon Avenue, Des Plaines, Illinois 60018, telephone (847) 294–7568.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments as they may desire. Comments that provide factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify the airspace docket number and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Airspace Docket No. 97–AGL–46.'' The postcard will be date/time stamped and returned to the commenter. All communications received on or before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of comments received. All comments submitted will be available for examination in the Rules Docket, FAA, Great Lakes Region, Office of the Assistant Chief Counsel, 2300 East Devon Avenue, Des Plaines, Illinois, both before and after the closing date for comments. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRM's

Any person may obtain a copy of this Notice of Proposed Rulemaking (NPRM) by submitting a request to the Federal Aviation Administration, Office of Public Affairs, Attention: Public Inquiry Center, APA–230, 800 Independence Avenue, SW., Washington, DC 20591, or by calling (202) 267–3484. Communications must identify the notice number of this NPRM. Persons interested in being placed on a mailing list for future NPRM's should also request a copy of Advisory Circular No. 11–2A, which describes the application procedure.

The Proposal

The FAA is considering an amendment to part 71 of the Federal Aviation Regulations (14 CFR part 71) to modify Class E airspace at London, OH. This additional airspace would accommodate aircraft executing the GPS RWY 08 SIAP at Madison County Airport by increasing the radius and enlarging the west extension of the existing controlled airspace. Controlled airspace extending upward from 700 to 1200 feet AGL is needed to contain aircraft executing the approach. The intended effect of this action is to provide segregation of aircraft using instrument approach procedures in instrument conditions from other aircraft operating in visual weather conditions. The area would be depicted on appropriate aeronautical charts. Class E airspace designations for airspace areas extending upward from 700 feet or more above the surface of the earth are published in paragraph 6005 of FAA Order 7400.9E, dated September 10, 1997, and effective September 16, 1997, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document would be published subsequently in the Order.

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore this, proposed regulation—(1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this proposed rule will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend part 71 of the Federal Aviation Regulations (14 CFR part 71) as follows:

PART 71—[AMENDED]

1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.9E, Airspace Designations and Reporting Points, dated September 10, 1997, and effective September 16, 1997, is amended as follows:

Paragraph 6005 The Class E airspace areas extending upward from 700 feet or more above the surface of the earth.

* * * * *

AGL OH E5 London, OH [Revised]

Madison County Airport, OH
(Lat. 39°55′58″ N, long. 83°27′43″ W)

That airspace extending upward from 700 feet above the surface within a 6.4-mile radius of the Madison County Airport and within 3.7 miles each side of the 267° bearing from the airport extending from the 6.4-mile radius to 7.4 miles west of the airport.

* * * * *

Issued in Des Plaines, Illinois on September 15, 1997.

Maureen Woods,

Manager, Air Traffic Division.

[FR Doc. 97–27390 Filed 10–16–97; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 97–AGL–43]

Proposed establishment of Class E Airspace; Bottineau, ND

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: This proposed rule would establish Class E airspace at Bottineau, ND. A Global Positioning System (GPS) Standard Instrument Approach Procedure (SIAP) to Runway (RWY) 31 has been developed for Bottineau Municipal Airport. Controlled airspace extending upward from 700 to 1200 feet above ground level (AGL) and upward from 1200 feet AGL is needed to contain aircraft executing the approach. The intended effect of this proposal is to provide segregation of aircraft using instrument approach procedures in instrument conditions from other aircraft operating in visual weather conditions.

DATES: Comment must be received on or before November 17, 1997.

ADDRESSES: Send comments on the proposal in triplicate to: Federal Aviation Administration, Office of the Assistant Chief Counsel, AGL–7, Rules Docket No. 97–AGL–43, 2300 East Devon Avenue, Des Plaines, Illinois 60018.

The official docket may be examined in the Office of the Assistant Chief Counsel, Federal Aviation Administration, 2300 East Devon Avenue, Des Plaines, Illinois. An informal docket may also be examined during normal business hours at the Air Traffic Division, Operations Branch, Federal Aviation Administration, 2300 East Devon Avenue, Des Plaines, Illinois.

FOR FURTHER INFORMATION CONTACT: Michelle M. Behm, Air Traffic Division, Airspace Branch, AGL–520, Federal Aviation Administration, 2300 East Devon Avenue, Des Plaines, Illinois 60018, telephone (847) 294–7568.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify the airspace docket number and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Airspace Docket No. 97–AGL–43.'' The postcard will be date/

time stamped and returned to the commenter. All communications received on or before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of comments received. All comments submitted will be available for examination in the Rules Docket, FAA, Great Lakes Region, Office of the Assistant Chief Counsel, 2300 East Devon Avenue, Des Plaines, Illinois, both before and after the closing date for comments. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRM's

Any person may obtain a copy of this Notice of Proposed Rulemaking (NPRM) by submitting a request to the Federal Aviation Administration, Office of Public Affairs, Attention: Public Inquiry Center, APA–230, 800 Independence Avenue, S.W., Washington, DC 20591, or by calling (202) 267–3484. Communications must identify the notice number of this NPRM. Persons interested in being placed on a mailing list for future NPRM's should also request a copy of Advisory Circular No. 11–2A, which describes the application procedure.

The Proposal

The FAA is considering an amendment to part 71 of the Federal Aviation Regulations (14 CFR part 71) to establish Class E airspace at Bottineau, ND, to accommodate aircraft executing the GPS RWY 31 SIAP at Bottineau Municipal Airport. Controlled airspace extending upward from 700 and 1200 feet AGL is needed to contain aircraft executing the approach. The intended effect of this action is to provide segregation of aircraft using instrument approach procedures in instrument conditions from other aircraft operating in visual weather conditions. The area would be depicted on appropriate aeronautical charts. Class E airspace designations for airspace areas extending upward from 700 feet or more above the surface of the earth are published in paragraph 6005 of FAA Order 7400.9E, dated September 10, 1997, and effective September 16, 1997, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document would be published subsequently in the Order.

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore this, proposed regulation—(1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this proposed rule will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend part 71 of the Federal Aviation Regulations (14 CFR part 71) as follows:

PART 71—[AMENDED]

1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9E, Airspace Designations and Reporting Points, dated September 10, 1997, and effective September 16, 1997, as amended as follows:

Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.

* * * * *

AGL ND E5 Bottineau, ND [New]

Bottineau Municipal Airport, ND
(Lat. 48°49′49″N, long. 100°25′00″W)

That airspace extending upward from 700 feet above the surface within a 6.4-mile radius of the Bottineau Municipal Airport and that airspace extending upward from 1200 feet above the surface within an area bounded on the north by latitude 49°00′00″N, on the east by longitude 99°49′00″W, on the south by the 10.5-mile radius of the Rugby, ND, Class E airspace, and on the west by the 47-mile radius of the Minot, ND, Class E airspace.

* * * * *

Issued in Des Plaines, Illinois on September 15, 1997.

Maureen Woods,

Manager, Air Traffic Division.

[FR Doc. 97–27392 Filed 10–16–97; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 97–AGL–45]

Proposed Modification of Class E Airspace; Mankato, MN

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: This proposed rule would modify Class E airspace at Mankato, MN. A Global Positioning System (GPS) Standard Instrument Approach Procedure (SIAP) to Runway (RWY) 22 and a Very High Frequency Omnidirectional Range/Distance Measuring Equipment (VOR/DME) or GPS SIAP to RWY 33 have been developed for Mankato Municipal Airport. Controlled airspace extending upward from the surface is needed to contain aircraft executing these approaches. This proposal would increase the radius of the surface area and add an extension to the northeast for the existing controlled airspace. The intended effect of this proposal is to provide segregation of aircraft using instrument approach procedures in instrument conditions from other aircraft operating in visual weather conditions.

DATES: Comments must be received on or before November 17, 1997.

ADDRESSES: Send comments on the proposal in triplicate to: Federal Aviation Administration, Office of the Assistant Chief Counsel, AGL–7, Rules Docket No. 97–AGL–45, 2300 East Devon Avenue, Des Plaines, Illinois 60018.

The official docket may be examined in the Office of the Assistant Chief Counsel, Federal Aviation Administration, 2300 East Devon Avenue, Des Plaines, Illinois. An informal docket may also be examined during normal business hours at the Air Traffic Division, Operations Branch, Federal Aviation Administration, 2300 East Devon Avenue, Des Plaines, Illinois.

FOR FURTHER INFORMATION CONTACT: Michelle M. Behm, Air Traffic Division, Airspace Branch, AGL–520, Federal

Aviation Administration, 2300 East Devon Avenue, Des Plaines, Illinois 60018, telephone (847) 294–7568.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify the airspace docket number and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Airspace Docket No. 97–AGL–45.'' The postcard will be date/time stamped and returned to the commenter. All communications received on or before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of comments received. All comments submitted will be available for examination in the Rules Docket, FAA, Great Lakes Region, Office of the Assistant Chief Counsel, 2300 East Devon Avenue, Des Plaines, Illinois, both before and after the closing date for comments. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRM's

Any person may obtain a copy of this Notice of Proposed Rulemaking (NPRM) by submitting a request to the Federal Aviation Administration, Office of Public Affairs, Attention: Public Inquiry Center, APA–230, 800 Independence Avenue, S.W., Washington, DC 20591, or by calling (202) 267–3484. Communications must identify the notice number of this NPRM. Persons interested in being placed on a mailing list for future NPRM's should also request a copy of Advisory Circular No. 11–2A, which describes the application procedure.

The Proposal

The FAA is considering an amendment to part 71 of the Federal Aviation Regulations (14 CFR part 71) to modify Class E airspace at Mankato, MN, to accommodate aircraft executing the GPS RWY 22 SIAP and the VOR/DME or GPS RWY 33 SIAP at Mankato Municipal Airport by increasing the radius of the surface area and adding a northeast extension to the existing controlled airspace. Controlled airspace extending upward from the surface is needed to contain aircraft executing these approaches. The intended effect of this action is to provide segregation of aircraft using instrument approach procedures in instrument conditions from other aircraft operating in visual weather conditions. The area would be depicted on appropriate aeronautical charts. Class E airspace designations for airspace areas designated as a surface area for an airport are published in paragraph 6002, and Class E airspace designations for airspace areas extending upward from 700 feet or more above the surface of the earth are published in paragraph 6005X of FAA Order 7400.9E, dated September 10, 1997, and effective September 16, 1997, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document would be published subsequently in the Order.

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore this proposed regulation—(1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this proposed rule will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend part 71 of the Federal Aviation Regulations (14 CFR part 71) as follows:

PART 71—[Amended]

1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9E, Airspace Designations and Reporting Points, dated September 10, 1997, and effective September 16, 1997, is amended as follows:

Paragraph 6002 The Class E airspace areas designated as a surface area for an airport.

* * * * *

AGL MN E2 Mankato, MN [Revised]

Mankato Municipal Airport, MN
(Lat. 44°13′18″N, long. 93°55′08″W)
Mankato VOR/DME
(Lat. 44°13′12″N, long. 93°54′44″W)

Within a 4.1-mile radius of Mankato Municipal Airport and within 1.8 miles each side of the Mankato VOR/DME 167° radial, extending from the 4.1-mile radius to 7 miles south of the VOR/DME, and within 2.7 miles each side of the Mankato VOR/DME 326° radial, extending from the 4.1-mile radius to 7 miles northwest of the VOR/DME. This Class E airspace is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Airport/Facility Directory.

* * * * *

Paragraph 6005 The Class E airspace areas extending upward from 700 feet or more above the surface of the earth.

* * * * *

AGL MN E5 Mankato, MN [Revised]

Mankato Municipal Airport, MN
(Lat. 44°13′18″N, long. 93°55′08″W)

That airspace extending upward from 700 feet above the surface within a 7-mile radius of Mankato Municipal Airport and within 2 miles each side of the 047° bearing from the airport, extending from the 7-mile radius to 8 miles northeast of the airport.

* * * * *

Issued in Des Plaines, Illinois on September 15, 1997.

Maureen Woods,

Manager, Air Traffic Division.

[FR Doc. 97–27394 Filed 10–16–97; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 97–AEA–41]

Proposed Amendment to Class E Airspace; York, PA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: This proposed rule would amend the Class E airspace area at York, PA. The development of a new Standard Instrument Approach Procedure (SIAP) based on the Global Positioning System (GPS), and amendments to existing SIAPs at York Airport has made this proposal necessary. Additional controlled airspace extending upward from 700 feet Above Ground Level (AGL) is needed to accommodate the SIAPs and for Instrument Flight Rules (IFR) operations at the airport.

DATES: Comments must be received on or before November 17, 1997.

ADDRESSES: Send comments on the proposal in triplicate to: Manager, Airspace Branch, AEA–520, Docket No. 97–AEA–41, F.A.A. Eastern Region, Federal Building #111, John F. Kennedy Int'l Airport, Jamaica, NY 11430.

The official docket may be examined in the Office of the Assistant Chief Counsel, AEA–7, F.A.A. Eastern Region, Federal Building #111, John F. Kennedy International Airport, Jamaica, New York 11430.

An informal docket may also be examined during normal business hours in the Airspace Branch, Airspace Branch, AEA–520, F.A.A. Eastern Region, Federal Building #111, John F. Kennedy International Airport, Jamaica, NY 11430.

FOR FURTHER INFORMATION CONTACT: Mr. Francis T. Jordan, Jr., Airspace Specialist, Airspace Branch, AEA–520 F.A.A. Eastern Region, Federal Building #111, John F. Kennedy International Airport, Jamaica, New York 11430; telephone (718) 553–4521.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, economic, environmental, and energy-related aspects of the proposal. Communications should identify the airspace docket number and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Airspace Docket No. 97–AEA–41.'' The postcard will be date/time stamped and returned to the commenter. All communications received on or before the closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of comments received. All comments submitted will be available for examination in the Rules Docket both before and after the closing date for comments. A report summarizing each substantive public contact with the FAA pesonnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

Any person may obtain a copy of this Notice of Proposed Rulemaking (NPRM) by submitting a request to the Office of the Assistant Chief Counsel, AEA–7, F.A.A. Eastern Region, Federal Building #111, John F. Kennedy International Airport, Jamaica, NY 11430. Communications must identify the notice number of this NPRM. Persons interested in being placed on a mailing list for future NPRMs should also request a copy of Advisory Circular No. 11–2A, which describes the application procedure.

The Proposal

The FAA is considering an amendment to Part 71 of the Federal Aviation Regulations (14 CFR Part 71) to amend the Class E airspace area at York, PA. A GPS RWY 17 SIAP has been developed, and the GPS RWY 35 SIAP and the NDB RWY 17 SIAP have been amended for the York Airport. Additional controlled airspace extending upward from 700 feet AGL is needed to accommodate the SIAPs and for IFR operations at the airport. Class E airspace designations for airspace areas extending upward from 700 feet or more above the surface of the earth are published in Paragraph 6005 of FAA Order 7400.9E, dated September 10, 1997, and effective September 16, 1997, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document would be published subsequently in the Order.

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this proposed regulation—(1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that would only affect air traffic procedures and air navigation, it is certified that this proposed rule would not have significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—[AMENDED]

1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.9E, Airspace Designations and Reporting Points, dated September 10, 1997, and effective September 16, 1997, is amended as follows:

Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.

* * * * *

AEA PA E5 York, PA [Revised]

York Airport, PA
(Lat. 39°55′05″N., long. 76°52′26″W.)
York NDB
(Lat. 39°55′12″N., long. 76°52′39″W.)

That airspace extending upward from 700 feet above the surface within a 6.5-mile radius of York Airport and within 4 miles each side of the 155° bearing from the York Airport extending from the 6.5-mile radius to 11 miles southeast of the airport and 4 miles west and 6 miles east of the 339° bearing from the York NDB extending from the 6.5-mile radius to 11 miles north of the NDB, excluding that portion that coincides with the Harrisburg, PA, Class E airspace area.

* * * * *

Issued in Jamaica, New York, on September 16, 1997.

Franklin D. Hatfield,

Manager, Air Traffic Division, Eastern Region.

[FR Doc. 97–27397 Filed 10–16–97; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 901

[SPATS No. AL–067–FOR]

Alabama Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

ACTION: Proposed Rule; Reopening and Extension of Public Comment Period on Proposed Amendment.

SUMMARY: OSM is announcing receipt of revisions pertaining to a previously proposed amendment to the Alabama regulatory program (hereinafter referred to as the ''Alabama program'') under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). The revisions for Alabama's proposed rules pertain to Rule 880–X–5A–.22, Orders and Decisions; and Rules 880–X–10C–.40 and 880–X–10D–.36, Coal Mine Waste: Refuse Piles (Surface Mining Activities and Underground Mining Activities, respectively). The amendment is intended to provide additional safeguards, clarify ambiguities, and improve operational efficiency.

DATES: Written comments must be received by 4:00 p.m., c.d.t., November 3, 1997.

ADDRESSES: Written comments should be mailed or hand delivered to Arthur W. Abbs, Director, Birmingham Field Office at the address listed below.

Copies of the Alabama program, the proposed amendment, and all written comments received in response to this document will be available for public review at the addresses listed below during normal business hours, Monday through Friday, excluding holidays. Each requester may receive one free copy of the proposed amendment by contacting OSM's Birmingham Field Office.

Arthur W. Abbs, Director, Birmingham Field Office, Office of Surface Mining Reclamation and Enforcement, 135 Gemini Circle, Suite 215, Homewood, Alabama 35209, Telephone: (205) 290–7282.

Alabama Surface Mining Commission, 1811 Second Avenue, P.O. Box 2390, Jasper, Alabama 35502–2390, Telephone (205) 221–4130.

FOR FURTHER INFORMATION CONTACT: Arthur W. Abbs, Director, Birmingham Field Office, Telephone: (205) 290–7282.

SUPPLEMENTARY INFORMATION:

I. Background on the Alabama Program

On May 20, 1982, the Secretary of the Interior conditionally approved the Alabama program. Background information on the Alabama program, including the Secretary's findings, the disposition of comments, and the conditions of approval can be found in the May 20, 1982, **Federal Register** (47 FR 22062). Subsequent actions concerning the conditions of approval and program amendments can be found at 30 CFR 901.15 and 901.16.

II. Discussion of the Proposed Amendment

By letter dated March 28, 1997, (Administrative Record No. AL–0562), Alabama submitted a proposed amendment to its program pursuant to SMCRA. Alabama submitted the proposed amendment at its own initiative. The provisions of the Alabama Surface Mining Commission Rules that Alabama proposes to amend are: Rule 88–X–5A–.22, Orders and Decisions; Rule 880–X6A–.06, License Application Requirements; Rule 880–X–7B–.07, Procedures for Permit Application Review; Rule 880–X–9E–.05, Determination of Forfeiture Amount; Rule 880–X–10C–.23, Hydrologic Balance: Surface and Ground Water Monitoring; Rule 880–X–10C–.36, Disposal of Excess Spoil (Surface Mining Activities); Rule 880–X–10C–.38, Coal Mine Waste: General Requirements (Surface Mining Activities); Rule 880–X–10C–.40, Coal Mine Waste: Refuse Piles (Surface Mining Activities); Rule 880–X–10D–.33, Disposal of Excess Spoil and Underground Development Waste (Underground Mining Activities); Rule 880–X–10D–.34, Coal Mine Waste: General Requirements (Underground Mining Activities); and Rule 880–X–10D–.36, Coal Mine Waste: Refuse Piles (Underground Mining Activities).

OSM announced receipt of the proposed amendment in the April 25, 1997, **Federal Register** (62 FR 20138) and invited public comment on its adequacy. The public comment period ended May 27, 1997.

During its review of the amendment, OSM identified concerns relating to Rule 880–X–5A–.22, Orders and Decisions; Rule 880–X–10C–.40, Coal Mine Waste: Refuse Piles (Surface Mining Activities); and Rule 880–X–10D–.36, Coal Mine Waste: Refuse Piles (Underground Mining Activities). On June 16, 1997, OSM notified Alabama of the concerns by telephone and by fax (Administrative Record No. AL–0572). Alabama responded in a letter dated July 30, 1997, (Administrative Record No. AL–0572) by submitting a revision to the amendment and additional explanatory information.

Alabama proposes revisions to Rule 880–X–5A–.22, Orders and Decisions; Rule 880–X–10C–.40, Coal Mine Waste: Refuse Piles (Surface Mining Activities); and Rule 880–X–10D–.36, Coal Mine Waste: Refuse Piles (Underground Mining Activities).

Specifically, Alabama proposes at Rule 880–X–5A–.22, Orders and Decisions, to change from 60 days to 30 days the time in which the hearing officer must make a written decision after the close of any hearing. For Rule 880–X–10C–.40, Coal Mine Waste: Refuse Piles (Surface Mining Activities) and Rule 880–X–10D–.36, Coal Mine Waste: Refuse Piles (Underground Mining Activities), Alabama proposes to issue a policy statement clarifying that the phrase ''safety factor'' means ''static safety factor.''

III. Public Comment Procedures

OSM is reopening the comment period on the proposed Alabama program amendment to provide the public an opportunity to reconsider the adequacy of the proposed amendment in light of the additional materials submitted. In accordance with the provisions of 30 CFR 732.17(h), OSM is seeking comments on whether the proposed amendment satisfies the applicable program approval criteria of 30 CFR 732.15. If the amendment is deemed adequate, it will become part of the Alabama program.

Written Comments

Written comments should be specific, pertain only to the issues proposed in this rulemaking, and include explanations in support of the commenter's recommendations. Comments received after the time indicated under **DATES** or at locations other than the Birmingham Field Office will not necessarily be considered in the final rulemaking or included in the Administrative Record.

IV. Procedural Determinations

Executive Order 12866

This proposed rule is exempted from review by the Office of Management and Budget (OMB) under Executive Order 12866 (Regulatory Planning and Review).

Executive Order 12988

The Department of the Interior has conducted the reviews required by section 3 of Executive Order 12988 (Civil Justice Reform) and has determined that, to the extent allowed by law, this rule meets the applicable standards of subsections (a) and (b) of that section. However, these standards are not applicable to the actual language of State regulatory programs and program amendments since each such program is drafted and promulgated by a specific State, not by OSM. Under sections 503 and 505 of SMCRA (30 U.S.C. 1253 and 1255) and 30 CFR 730.11, 732.15, and 732.17(h)(10), decisions on proposed State regulatory programs and program amendments submitted by the States must be based solely on a determination of whether the submittal is consistent with SMCRA and its implementing Federal regulations and whether the other requirements of 30 CFR Parts 730, 731, and 732 have been met.

National Environmental Policy Act

No environmental impact statement is required for this rule since section 702(d) of SMCRA (30 U.S.C. 1292(d)) provides that agency decisions on proposed State regulatory program provisions do not constitute major Federal actions within the meaning of section 102(2)(C) of the National Environmental Policy Act (42 U.S.C. 4332(2)(C)).

Paperwork Reduction Act

This rule does not contain information collection requirements that require approval by OMB under the Paperwork Reduction Act (44 U.S.C. 3507 *et seq.*).

Regulatory Flexibility Act

The Department of the Interior has determined that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). The State submittal which is the subject of this rule is based upon counterpart Federal regulations for which an economic analysis was prepared and certification made that such regulations would not have a significant economic effect upon a substantial number of small entities. Accordingly, this rule will ensure that existing requirements previously promulgated by OSM will be implemented by the State. In making the determination as to whether this rule would have a significant economic impact, the Department relied upon the data and assumptions for the counterpart Federal regulations.

Unfunded Mandates

OSM has determined and certifies pursuant to the Unfunded Mandates Reform Act (2 U.S.C. 1502 *et seq.*) that this rule will not impose a cost of $100 million or more in any given year on local, state, or tribal governments or private entities.

List of Subjects in 30 CFR Part 901

Intergovernmental relations, Surface mining, Underground mining.

Dated: October 9, 1997.

Charles E. Sandberg,

Acting Regional Director, Mid-Continent Regional Coordinating Center.

[FR Doc. 97–27624 Filed 10–16–97; 8:45 am]

BILLING CODE 4310–05–M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[TX27–1–5945; FRL–5910–2]

Approval and Promulgation of Air Quality State Implementation Plans (SIP); Texas; Disapproval of Texas Clean Fuel Fleet Program Revision to the State Implementation Plan

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed disapproval.

SUMMARY: The EPA is proposing disapproval of the Texas Clean Fuel Fleet (CFF) SIP revision submitted on August 9, 1996, by the State of Texas for the purpose of establishing a substitute CFF program. The EPA is disapproving the State's SIP revision due to changes in the State law that altered the current SIP revision submittal and because, in EPA's opinion, the State did not make a convincing and compelling equivalency determination with the Federal CFF program.

DATES: Comments must be received on or before November 17, 1997.

ADDRESSES: Written comments on this action should be addressed to Mr. Thomas H. Diggs, Chief, Air Planning Section, Environmental Protection Agency, Region 6, 1445 Ross Avenue, Suite 700, Dallas, Texas 75202–2733. Copies of the documents about this action are available for public inspection during normal business hours at the following locations. Persons interested in examining these documents should make an appointment with the appropriate office at least 24 hours before the visiting day.

Environmental Protection Agency, Region 6, Air Planning Section (6PD–L), 1445 Ross Avenue, Suite 700, Dallas, Texas, 78711–3087.

Texas Natural Resource Conservation Commission, 12100 Park 35 Circle, Austin, Texas 78711–3087.

FOR FURTHER INFORMATION CONTACT: Mr. Paul Scoggins, Air Planning Section (6PD–L), EPA Region 6, 1445 Ross Avenue, Dallas, Texas 75202–2733, telephone (214) 665–7354 or via e-mail at scoggins.paul@epamail.epa.gov. While information may be requested via e-mail, all comments must be submitted in writing to the EPA Region 6 address above.

SUPPLEMENTARY INFORMATION:

I. Background

On November 15, 1990, Congress enacted amendments to the 1997 Clean Air Act (the Act); Pub. L. 101–549, 104 Stat. 2399, codified at 42 U.S.C. 7401–7671q. The CFF program is contained under part C, entitled, ''Clean Fuel Vehicles,'' of Title II of the Act, as amended November 15, 1990. Part C was added to the Act to establish two programs: a clean-fuel vehicle pilot program in the State of California (the California Pilot Test Program) and the Federal CFF program in certain ozone and carbon monoxide nonattainment areas.

Section 182(c)(4) of the Act, 42 U.S.C. 7511a (c)(4), allows states to opt-out of the Federal CFF program by submitting, for EPA approval, a SIP revision consisting of a substitute program resulting in as much or greater long term emissions reductions in ozone producing and toxic air emissions as the Federal CFF program. The EPA may approve such a revision only if it consists exclusively of provisions other than those required under this Act for the area.

The State of Texas chose to opt-out of the Federal CFF program in a committal SIP revision submitted to EPA on November 15, 1992. In July 1994, Texas submitted the State's opt-out program in a SIP revision to EPA and adopted rules to implement the Texas CFF Program. The Texas CFF SIP was revised based upon changes to State law and resubmitted to EPA on August 6, 1996. On June 20, 1997, the Governor of Texas signed into law Senate Bill 681 that modified the supporting legislation (Chapter 382 of the Texas Health and Safety Code) for the current submitted revision.

II. EPA Analysis of State Submittal

The EPA is proposing disapproval based on the finding that changes to the supporting legislation have altered the August 6, 1996, submitted SIP revision.

As a result, the specific legislative authority in the submission is no longer in effect. In addition to the above changes, Texas's technical and equivalency method has not identified and quantified accurately the covered fleets in the Federal and State covered areas. The Texas CFF program has excluded certain covered fleets from its total fleet aggregation in the El Paso and Houston/Galveston nonattainment areas. Without an adequate determined fleet baseline for comparison, the SIP revision's technical evaluation is not sufficiently comprehensive to determine equivalency with the Federal CFF program. These and additional concerns with the State CFF program and broad compliance exemptions lead EPA to conclude that the State has not made a convincing and compelling demonstration of equivalency with the Federal CFF program. A more detailed discussion of the Texas CFF program elements and control strategy can be found in the Technical Support Document available from the EPA Region VI office.

III. Proposed Action

The EPA is proposing disapproval of the Texas CFF SIP revision submitted to EPA on August 6, 1996. The State's proposed substitute program is codified in 30 Texas Administrative Code, Chapter 114, Sections 114.30, 114.32 through 114.34, and 114.36 through 114.40. The EPA is soliciting public comments on the proposed action discussed in this notice. These comments will be considered before taking final action. Interested parties may participate in the Federal rulemaking procedure by submitting written comments to the EPA Regional office listed in the **ADDRESSES** section of this notice.

The regional office, with EPA's Office of Mobile Sources has initiated efforts to help ensure that this action is consistent with the Act and will not interfere with any applicable requirement concerning attainment or any other applicable requirement of the Act.

Nothing in this action should be construed as permitting or allowing or establishing a precedent for any future request for revision to any SIP. Each request for revision to the SIP will be considered separately in light of specific technical, economic, and environmental factors and in relation to relevant statutory and regulatory requirements.

IV. State Options

The following are options available to Texas in the implementation of its CFF Program. The State may choose to; adopt the Federal CFF Program; or revise the current Texas CFF program and resubmit to EPA or substitute another State program or control strategy for the Texas CFF program. Such a substitution could be a stationary or mobile source control program, but only if it consists exclusively of provisions other than those required under the Act.

V. Administrative Requirements

A. Executive Order (E.O.) 12866

The Office of Management and Budget has exempted this regulatory action from E.O. 12866 review.

B. Regulatory Flexibility Act

Under the Regulatory Flexibility Act, 5 U.S.C. 600 *et seq.*, EPA must prepare a regulatory flexibility analysis assessing the impact of any proposed or final rule on small entities. See 5 U.S.C. 603 and 604. Alternatively, EPA may certify that the rule will not have a significant impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and government entities with jurisdiction over populations of less than 50,000.

The EPA's disapproval of the State request under section 110 and subchapter I, part D of the Act does not affect any existing requirements applicable to small entities. Any preexisting Federal requirements remain in place after this disapproval. Federal disapproval of the State submittal does not affect its State enforceability. Moreover, EPA's disapproval of the submittal does not impose any new Federal requirements. Therefore, EPA certifies that this disapproval action does not have a significant impact on a substantial number of small entities because it does not remove existing requirements and impose any new Federal requirements.

C. Unfunded Mandates

Under section 202 of the Unfunded Mandates Reform Act of 1995, signed into law on March 22, 1995, EPA must prepare a budgetary impact statement to accompany any proposed or final rule that includes a Federal mandate that may result in estimated costs to State, local, or tribal governments in the aggregate or to private sectors, of $100 million or more. Under section 205, EPA must select the most cost-effective and least burdensome alternative that achieves the objectives of the rule and is consistent with statutory requirements. Section 203 requires EPA to establish a plan for informing and advising any small governments that may be significantly or uniquely impacted by the rule.

The EPA has determined that the disapproval action proposed does not include a Federal mandate that may result in estimated costs of $100 million or more to either State, local, or tribal governments in the aggregate, or to the private sector. This Federal action imposes no new requirements. Accordingly, no additional costs to State, local, or tribal governments, or to the private sector, result from this action.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Hydrocarbons, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Ozone, Reporting and Recordkeeping requirements.

Dated: October 8, 1997.

Jerry Clifford,

Acting Regional Administrator.

[FR Doc. 97–27622 Filed 10–16–97; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention (CDC)

42 CFR Part 84

National Institute for Occupational Safety and Health; Certification of Respiratory Devices Used to Protect Workers in Hazardous Environments

AGENCY: National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (DHHS).

ACTION: Notice of priorities for rulemaking.

SUMMARY: In response to public comments received from its May 16, 1996, request (61 FR 24740), NIOSH is announcing the intended priority order for the development of the next proposed rule amendments (modules) to the current NIOSH procedures for certifying respiratory devices used to protect workers in hazardous environments. The priority order is based on the comments and data in the public record. The priority order of the planned modules is provided to help the respirator community plan for potential changes.

FOR FURTHER INFORMATION CONTACT: Roland Berry Ann, NIOSH, 1095 Willowdale Road, Morgantown, West

Virginia 26505–2888, telephone (304) 285–5907.

Availability and access of copies: Additional copies of this notice can be obtained by calling the NIOSH toll-free information number (1–800–35-NIOSH, option 5, 9 a.m.–4 p.m. ET); the electronic bulletin board of the Government Printing Office, (202) 512–1387; and the NIOSH Home Page on the World-Wide Web (http://www.cdc.gov/niosh/homepage.html).

SUPPLEMENTARY INFORMATION: NIOSH intends to propose technical modules in the following areas:

1. Powered Air Purifying Respirator (PAPR)—Establishment of N, R, and P series filters; Use of active low flow or low pressure warning devices; and Addition of new duration ratings.
2. Airline Respirator—Single airline for pneumatic devices and breathing air; Airline suits (i.e., Department of Energy/Los Alamos National Laboratory suits); Metabolic simulator tests; Air flow/pressure rate requirements; and Air flow measuring and warning devices.
3. Self Contained Breathing Apparatus (SCBA)—Maximum weight limit, with accessory definition; Upgrade of cylinder air specifications; Incorporation of National Fire Protection Association (NFPA) requirements; Non-facepiece SCBA; Metabolic simulator tests; Air flow/pressure rate requirements; and Alternatives to Department of Transportation and Compressed Gas Association requirements.
4. Gas and Vapor Respirator—Certification to a wider variety of specific substances and addition of service life categories.

NIOSH intends to propose three Administrative/Quality Assurance modules. The intended subjects for these modules are:

1. Corrections to 42 CFR part 84 and existing program policies not included in the regulations.
2. Upgrade of Quality Assurance requirements; Use of independent quality auditors in the certification program and updated fee schedule.
3. Use of independent testing laboratories in the certification program and restructured fee schedule.

I. Background

On May 16, 1996, NIOSH published a document in the **Federal Register** (61 FR 24740) to request public comments on what the agency's priorities should be in the area of respirator certification. NIOSH sought public comments on issues of privatization and fees related to possible changes in its administration of respirator certification, and comments on establishing priorities for future rulemaking. NIOSH held three public meetings in June 1996 to discuss these issues. All comments provided in response to the notice were considered in developing the rulemaking priorities.

II. Public Comment on Priority Issues

Thirty-two commenters responded to the document including: eleven respirator manufacturers, seven private sector testing and certification laboratories, five safety professionals, two public utilities, two trade or manufacturers' associations, one Federal agency, one National Laboratory, one fire department, one professional society, and one respirator accessory manufacturer.

III. Ranking Criteria for Technical Modules

NIOSH requested input on what determinants should be used as the criteria to rank the priority of each module, in addition to recommendations for module subject areas. The determinants for ranking listed in the notice were; consideration of the number of persons (workers) affected, the seriousness of hazards or problems that would be addressed, the extent to which changes would improve protection, opportunity for cost savings (reducing costs for manufacturers and purchasers of respirators) and the expediency by which a change could be implemented (e.g., the existence of adoptable consensus standards).

NIOSH specifically sought comments on the following issues for prioritizing the development of modules: the criteria to prioritize each module, existing national or international standards that could be adopted to replace current NIOSH certification requirements, and public health effects of any recommended changes.

A. Discussion of Comments Received

Commenters generally agreed with the determinants listed in the notice. Two commenters stated that allowing flexibility of design and innovative approaches to design and use, as well as encouraging new product development should be included in the priority ranking criteria.

B. Conclusions

NIOSH believes that the ability to use innovative approaches and flexibility in design results in new product development. Performance standards allow manufacturers to use innovative approaches and flexibility in design, resulting in new products to address hazards. NIOSH intends to develop performance-based technical criteria to the extent possible in its rulemaking activities. Therefore, although neither of these suggestions were included as determinants in the priority ranking criteria, NIOSH expects both will result from the rulemaking activities.

The ranking criteria used to develop the module priority order was: the number of workers affected, the seriousness of hazards or problems that would be addressed, the extent to which changes would improve protection, the expediency by which a change can be implemented (e.g., the existence of adoptable consensus standards), and opportunity for cost savings (reducing costs for manufacturers and purchasers of respirators).

IV. Technical Module Priority

NIOSH requested input to develop a complete, ranked list of priorities for rulemaking, including justification for the ranking. NIOSH specifically sought comments on the following issues for module development ranking: changes needed to current respirator certification requirements in the modules identified in the notice, subject areas for improving current certification requirements not identified in the notice, suggested module rankings, with ranking criteria and data or reasoning, industries and workers affected by potential changes, technical feasibility of suggested changes, economic impact to respirator manufacturers, purchasers, and users, and other factors related to the priority ranking.

A. Discussion of Comments Received

NIOSH has developed a ranked list of priorities for rulemaking, including justification for the ranking based on the comments received. Areas recommended for modification by commenters were grouped into feasible modules, then ranked according to the priority ranking criteria. The ranking justifications, based on the available supporting information, are included with the listing of the identified modules in IV.B. Conclusions.

The purpose of this notice is to inform the respirator community of regulatory priorities to allow research and planning to be coordinated with the development of new standards. NIOSH research and development efforts will be directed primarily at the highest priority areas identified in this notice. NIOSH also encourages others in the respirator community to conduct research in the identified module areas.

Research results and planning information for the regulatory priorities identified in this notice should be submitted to the NIOSH docket when they become available. The information will then be in a forum for public

review and comment. The information received in the NIOSH docket will establish a database to help develop future regulatory proposals.

Most of the determinants in the ranking criteria are based up the agency's current understanding of the capabilities of the manufacturing community as well as the science upon which the product development is based. Chief among these is the expediency by which a change can be implemented. NIOSH has attempted to estimate the research needed for each identified module in this priority-ranking process. It must be recognized that module development will be based on the successful completion of research in most of the identified module areas. Therefore, the rulemaking order of the identified modules may vary slightly from the priority order identified in this notice.

B. Conclusions

The following module list identifies the priority assessment for development of technical improvements based on the information provided by commenters:

1. Powered Air Purifying Respirator (PAPR)

Areas for potential modification in this module are: Establishment of N, R, and P series filters; Use of active low flow or low pressure warning devices; and Addition of new duration ratings.

The regulations require the PAPR battery to have a service time sufficient to maintain a stated air flow throughout 4 hours of operation during a silica dust loading test with particulate filters.

One commenter stated that the current requirements result in units that are too heavy and burdensome for most applications. Another commenter specifically suggested that modifications should be made to allow a light weight hood type PAPR for the health-care industry.

One commenter recommended the requirement of low flow and negative pressure warning devices to assure workers are protected from overbreathing the PAPR air supply. This commenter also recommended the establishment of a pressure demand PAPR. Two other commenters suggested the use of these devices and breathing-assist devices to establish positive pressure and negative pressure classes of PAPR's. These commenters indicated that PAPR duration may be able to be defined by an active alarm from a low pressure or low flow sensor, signaling an end of the battery's service life.

Presently, the filter choices for use with PAPR's has been limited to only high efficiency particulate air (HEPA) filters with the implementation of part 84. Commenters indicated that additional choices are necessary.

Four commenters stated that the regulations should be modified to include the same filter classes for PAPR's as are provided for non-powered filter respirators under 42 CFR 84. PAPR filter testing was included in the proposed 42 CFR 84 (59 FR 26850), but was not included in the final rule because additional research is needed to make the proposed tests more feasible and consistent with the part 84 filter tests.

Seven commenters indicated that PAPR requirements should be the top priority for technical revision of the regulations. The possibility of increased worker protection with lighter, cheaper units was represented by most of these commenters.

Estimates of more than 500,000 PAPR users in chemical, health care, pharmaceutical, agriculture and welding were provided by a commenter.

2. Airline Respirator

Areas for potential modification in this module are: Single airline for pneumatic devices and breathing air; Airline suits (i.e., Department of Energy/Los Alamos National Laboratory suits); Metabolic simulator tests; Air flow/pressure rate requirements; and Air flow measuring and warning devices.

Presently, 42 CFR part 84 does not contain a respirator classification that allows a single airline to the person for pneumatic devices and breathing air. NIOSH has recommended against this practice due to concerns over potential contamination of the air supply, and the high potential for negative impacts on respirator performance. In the absence of a dedicated breathing-air system, there is an increased risk of a contaminated air supply and negative impacts on respirator performance due to: backflow of contaminants from the pneumatic device line to the respirator air supply, low air flow and pressure to the respirator from a severed pneumatic-tool line, and excessive air flow and pressure from a blocked pneumatic-tool line.

Four commenters asserted that the breathing air could be filtered to Grade D specifications at the person wearing the respirator (e.g. on the belt). They stated that technology is available to ensure that an air filtering system incorporated into a respirator design would provide Grade D breathing air at the wearer, and this design should be certified by NIOSH. One of the commenters indicated that by providing safeguards against robbing air from the respirator, or feedback from pneumatic tools, a criteria could be developed for supplied air respirators (SAR) that allow a single airline for tools and breathing air. The use of air flow or pressure devices were suggested to provide needed assurances and warning of appropriate user air supply. Three of the commenters indicated that appropriate European standards that NIOSH could adopt exist for such a respirator class.

Presently, there is a standardized set of exercises and work rate criteria used in the evaluation of SAR's. The use of a metabolic simulator for testing was recommended by two commenters to help eliminate the variability associated with human testing. According to several commenters, the criteria for certifying SAR's could be upgraded by modifying the class criteria to reflect differing work rates with minimum flow rates and pressure differential from atmosphere. This would result in new, additional classifications for SAR's. One commenter recommended the use of air flow volume measuring and low flow warning devices. Three commenters suggested that a positive pressure class be defined. Another commenter suggested that a positive pressure within the facepiece should be required at the tested work rate.

Two commenters stated that a criteria is needed for NIOSH-acceptance of airline suits for respiratory protection. These commenters asserted that airline suits (i.e., Department of Energy/Los Alamos National Laboratory suits) have been used for respiratory protection against hazardous and toxic substances for twenty years under a Department of Energy acceptance program. In addition to respiratory protection, one of the commenters stated that the suits provide benefits such as total body protection and relief of heat stress. A Los Alamos National Laboratory evaluation protocol (LA–10156–MS) was recommended for as an acceptable criteria by both commenters.

Estimates of 50,000 auto body shops with over 100,000 workers, with additional unnumbered workers in other industries were given by one commenter as potential users of single airline respirators.

Several commenters stated that workers were improperly protected because the NIOSH-certified supplied air respirators were not conducive to use because they require two airlines to separate pneumatic device air from breathing air. Estimates were given that less than 5% of U.S., more than 95% of British, and more than 90% of European auto painters use proper respirators. Cost savings and greater user acceptance were projected based on the possible

elimination of the installation and maintenance of a second airline.

3. Self Contained Breathing Apparatus (SCBA)

Areas for potential change in this module are: maximum weight limit, with accessory definition; Upgrade of cylinder air specifications; Incorporation of NFPA requirements; Non-facepiece SCBA; Metabolic simulator tests; Air flow/pressure rate requirements.

Presently, 42 CFR part 84 limits the weight of a completely assembled and fully charged SCBA apparatus to 35 pounds for most units. A maximum weight of 40 pounds is allowed only where the weight decreases by more than 25 percent of its initial charge weight during its rated service life or where an apparatus employs a cooling system. NIOSH does not include the weight of accessories in the total weight of a respirator.

Four commenters suggested that the maximum weight limit of an SCBA apparatus should be permitted to exceed 35 pounds where other fire fighter protective clothing or equipment is incorporated with the SCBA. One of them recommended a definition for accessories is needed to better define those items not included in the weight calculation. These commenters stated that this change could result in more comfort, greater protection, and a lower overall ensemble weight for fire fighters.

Presently, there is a standardized set of exercises and work rate criteria used in the evaluation of air supplied respirators. According to several commenters, the criteria for certifying SCBA's could be upgraded by modifying the class criteria to reflect differing work rates with minimum flow rates and pressure differential from atmosphere. This would result in new, additional classifications specifically for SCBA's. One commenter recommended the use of air flow volume measuring and low flow warning devices. Three commenters suggested that a positive pressure class be defined. Another commenter suggested that a positive pressure within the facepiece should be required at the tested work rate. One commenter suggested that the requirements for open circuit apparatus should be separated from the requirements for closed circuit apparatus.

The use of a metabolic simulator for testing was recommended by two commenters to help eliminate the variability associated with human testing.

Incorporation of standards consistent with life support efficacy portions of the NFPA requirements were recommended to upgrade the current standards. Three commenters stated that some NFPA 1981–1992 requirements should be included in the NIOSH requirements. Higher air flow rates and lens abrasion resistance were provided as examples. One of these commenters recommended the incorporation of NFPA 1981–1992 for fire fighter SCBA, with some of the requirements applicable to all SCBA. This commenter also stated that the dew point and particulate level requirements of NFPA 1500–1992 should be required for SCBA cylinder air.

One commenter requested provisions be developed for NIOSH to approve SCBA without a facepiece. This commenter asserted that the National Aeronautics and Space Administration (NASA) has used non-facepiece, suit SCBA since the early 1960's without any serious problems. This commenter stated that similar suits are being developed for decontamination and decommissioning of Department of Energy sites and other chemical waste sites. The commenter recommended a revision to the regulations to allow NIOSH certification of this class of respirator.

One commenter suggested that NIOSH should accept alternatives to Department of Transportation (DOT) and Compressed Gas Association (CGA) cylinder requirements. This commenter asserted that a cylinder could be incorporated as an integral part of the SCBA design without a standardized CGA cylinder thread, which is design restrictive. The commenter also recommended that cylinder acceptances of other certifying agencies throughout the world be recognized as equivalent to the United State's DOT requirements. No user population size or overall user type estimates were provided by commenters for SCBA. However, NIOSH is aware of estimates of the number of fire fighters in the U.S. While not representing users of all SCBA, fire fighters are believed to be a significant portion of the SCBA user population.

According to the National Fire Protection Association's (NFPA) 1995 Fire Department Profile, there are 1,098,850 fire fighters (260,850 career and 838,000 volunteer) in the United States. According to the National Volunteer Fire Council, a non-profit membership association representing the interests of the volunteer fire, emergency medical, and rescue services, there are 1.5 million volunteer firefighters who staff more than 28,000 fire departments throughout the United States. The International Association of Fire Fighters (IAFF) represents over 225,000 professional fire fighters and emergency medical personnel in the United States and Canada. In 1992, NIOSH estimated 400,000 firefighter SCBA's were in use by some 200,000 full time and 1,000,000 volunteer and non-municipal firefighters in the U.S.

4. Gas and Vapor Respirator

Areas for potential modification in this module are: Certification to a wider variety of specific substances and addition of service life categories.

Presently, NIOSH certifies gas and vapor (chemical cartridges included) respirators only to provide protection against only sixteen specific substances. Gas mask canisters and chemical cartridges may be classified for protection against the general category of organic vapors. Gas mask canisters may also be classified for protection against the general category of acid gases. Their use against substances with poor warning properties has not been recommended.

One commenter stated that there is a need for a new class of respirators for protection against the accidental release or terroristic use of chemical agents. This commenter asserted that local law enforcement, first response teams, and local and state agencies are seeking and need NIOSH-certified respirators in responding to these events. The use of existing facilities that test and evaluate equipment against chemical warfare agents for the military was proposed as an alternative to new NIOSH facilities.

The current standards in 42 CFR 84 provide for a canister or cartridge absorption capacity test criteria based on the respirator type. Two commenters indicated that NIOSH-certified canisters and cartridges are heavy and bulky because of too severe service life requirements. They asserted that various service times (or sorbent capacities) could be appropriately used, based on the conditions of use. They recommended modifying the certification standards to include other service time possibilities and absorption capacities under additional test parameters. One of these commenters recommended the regulations be modified to allow for certification of three cartridge capacity sizes by using three challenge levels of exposure for certification, similar to the European standards.

No precise user population estimates were cited by commenters. Users were identified only as unnumbered workers such as law enforcement personnel and first response teams with accidental release of chemical agents and chemical warfare agents.

V. Notification of Revised Priority Assessment

A. Comment Request

NIOSH will readily notify respirator manufacturers directly about changes to the regulatory priorities established in this notice. NIOSH specifically sought comments on how respirator purchasers and users should be notified of revised priorities.

B. Discussion of Results

Commenters suggested various mechanisms for notifying respirator purchasers and users of revised priorities. One commenter suggested the use of a Respirator Users' Notice. Three commenters suggested the use of the NIOSH internet Web site. Three commenters recommended the information be published in safety industry newspapers, magazines, and newsletters like the BNA ''Occupational Safety and Health Reporter''. Two commenters suggested the use of another **Federal Register** notice. One commenter each suggested that the respirator manufacturers, sales and marketing managers, and major users groups like the American Industrial Hygiene Association (AIHA), Chemical Manufacturers Association (CMA), National Association of Manufacturers (NAM), and American Iron and Steel Institute (AISI) be used to notify respirator purchasers and users.

C. Conclusions

NIOSH has established the priorities for rulemaking based on the comments received to the May 16, 1996 request. However, these priorities may change as new needs are identified or unforeseen delays are encountered with research efforts. New modules may be needed to respond to emerging hazards and developing technology.

Commenters failed to reveal any new mechanisms for NIOSH use to better disseminate rulemaking priority updates. NIOSH has used respirator-related mailing lists (including the Users Notice List and Respirator Manufacturers List), the NIOSH internet Web site, the Government Printing Office electronic bulletin board, press releases, and the NIOSH toll-free information number to disseminate **Federal Register** notices.

Publication of the information in safety industry newspapers, magazines, and newsletters is dependent on the publishers' expectations of reader interest. Dissemination of the information by the respirator manufacturers, sales and marketing managers, and major users groups depends on their willingness and ability to relay the information to their clientele. NIOSH respirator-related mailing lists have historically been generated as a result of public comments or a request for respirator-related publications. World-Wide Web and electronic bulletin board listings rely on the reader to go to the site to find the information.

NIOSH will continue to disseminate **Federal Register** notices as in the past, while continuing to seek better notification methods.

VI. Administrative and Quality Assurance Issues

A. Private Sector Testing Laboratories

Specifically, NIOSH sought comments on the following issues for the potential use of private sector testing laboratories for the certification process:

- Capability of private sector testing laboratories to conduct the respirator testing currently performed by NIOSH.
- Qualification requirements of private laboratories if they were to perform certification and product audit testing under NIOSH guidance.
- Assignment of a manufacturer's respirators to testing laboratories by NIOSH or manufacturer choice among approved laboratories.
- Monitoring of private sector laboratories to assure quality service would be continued if they were to perform certification and product audit testing under NIOSH guidance.

1. Discussion of Comments Received

Many of the commenters endorsed, with reservation, the idea of empowering private sector testing laboratories to conduct the NIOSH certification testing. Concerns about NIOSH's ability to empower these laboratories were raised by most of the commenters. These concerns centered around (1) the existence of lab capability in the private sector, (2) impartiality and credibility of testing and (3) documentation of the NIOSH testing procedures and reproducibility of results.

Five commenters questioned the existence of testing laboratory capability in the private sector. Nine commenters supported the belief that private sector testing laboratories are capable of performing the NIOSH testing. Several of these commenters indicated that the testing ability and capacity currently exists with certification of self contained breathing apparatus to NFPA requirements. They further stated that added capacity would be quickly obtained for other respirators once the market was there.

Five commenters stated that the documentation of the NIOSH testing procedures need to be improved before other testing authorities should be authorized to conduct the certification testing. These commenters expressed concern that test results would not be reproducible among a number of testing facilities. That is, test results could vary from laboratory to laboratory without an inter-laboratory validation program.

Concerns were raised by several commenters that impartiality and credibility would be lost with the testing portion of the certification process removed from NIOSH control. One commenter was concerned that any laboratory not have any vested interest in the certification of products or with manufacturers. A few commenters indicated increased NIOSH staff would be more productive than using private sector laboratories. These commenters felt that NIOSH resources would be consumed with oversight of accredited laboratories.

Another commenter stated that the survivability of private sector testing laboratories depends on their ability to demonstrate impartiality and credibility in their test results. Several other commenters indicated that use of already established accreditation or certification programs would require little or no additional NIOSH oversight.

Four commenters indicated that the European experience with privatization and U.S. certification authorities such as the NFPA and Safety Equipment Institute (SEI) have been good. Experiences with favorable turnaround times and costs were reported.

Commenters recommended that NIOSH adopt an existing system, rather than create a new one. Three commenters recommended accreditation by the American National Standards Institute (ANSI) to ANSI Z34.1. This standard was judged inappropriate for lab privatization by another because it is a complete program that includes design, QA and product testing requirements for the certification of manufacturers' products by the authorized entity. This is similar to the current NIOSH process. ISO Guide 25, a tool to assess and accept a laboratory's calibration and QA procedures for accurate and consistent results, was recommended by four commenters. Two more commenters suggested that NIOSH should become ISO certified as well.

2. Conclusions

NIOSH agrees with those commenters who stated that the use of private sector testing laboratories could expedite the approval process and the availability of the latest and safest technology. This will be accomplished only if the use of

these laboratories increases the resources available to conduct the tests. NIOSH shares the concern expressed by some commenters that an insufficient business base may exist to assure the increased resources, quality level and cost would be acceptable.

Private sector testing laboratories can be utilized in the certification of respirators, provided that adequate procedures and safeguards are in place. No existing testing laboratory accreditation or certification programs have standards and procedures that accredit or certify laboratories to perform the NIOSH tests. The procedures and standards to accredit or certify testing laboratories to conduct the NIOSH tests need to be developed before a laboratory could be accredited. Clear, objective test requirements and protocols that provide test results reproducible between laboratories also need to be finalized and made available before most NIOSH tests can be used by private testing laboratories.

NIOSH has determined that there are private sector testing laboratories with the capability to perform the NIOSH tests. However, NIOSH is concerned that there is insufficient testing capacity to meet the demand for testing. NIOSH has seen no evidence that this capacity is present, especially considering the comments that refined procedures are needed to allow others to conduct the NIOSH tests. Efforts to develop testing laboratory certification and auditing criteria will consume some NIOSH resources to establish the program.

NIOSH is continuing to explore options for the potential use of private sector testing laboratories for the certification process. However, the infrastructure to define and support the use of these laboratories remains to be established. NIOSH intends to propose an Administrative module to address the use of private sector testing laboratories for the certification process after the infrastructure needs are better determined.

B. Private Sector Quality Auditors

Specifically, NIOSH sought comments on the following issues for the potential use of private sector quality auditors for the certification process:

- Qualification requirements (e.g., certification by ANSI-Registrar Accreditation Board, United Kingdom Accreditation Service, International Auditor and Training Certification Association, etc.) of independent quality auditors if they were to perform manufacturing site audits under NIOSH guidance.
- Assurances of integrity for a program using private quality auditors.
- Frequency of audits needed to assure that only quality products are distributed.
- Auditing of manufacturing sites prior to the issuance of a NIOSH certification.

1. Discussion of Comments Received

No commenters opposed the use of private sector quality auditors for the certification process. Three commenters endorsed the use of the International Organization of Standardization certification standards (ISO) for evaluation of the manufacturers' quality assurance systems. Two of these commenters pointed out that, specifically, ISO 9001 should be adopted because it documents the design and development process, unlike ISO–9002.

The ISO standards were perceived by several commenters as sufficient to ensure the integrity of the program. One commenter stated that the ISO system requires auditors to be certified by authorities such as Underwriters Laboratories. A commenter stated that NIOSH must develop the criteria for an acceptable quality assurance plan for use by an ISO auditor. Two commenters believed that ISO 9001 audits could be used instead of NIOSH audits because the ISO audit would ensure the quality assurance plan is met. These same commenters thought that the ISO semiannual or annual frequency of audit was appropriate.

Two commenters pointed out that ISO 9000 requires site audits prior to registration. Therefore, if a manufacturer has been ISO-certified, they stated no NIOSH pre-certification audit would be needed. If the manufacturer has not been ISO-certified or is a new manufacturer, they stated that a NIOSH pre-certification audit would be appropriate.

2. Conclusions

Qualified quality auditors may be used to perform site audits for verification that the manufacturers' quality systems are being followed and are appropriate. Empowering qualified auditors would expand the audit portion of the certification program to levels consistent with most contemporary certification authority requirements. NIOSH has been developing audit guidelines that could enable a qualified auditor to evaluate compliance with the salient points of a manufacturer's quality assurance plan.

NIOSH is evaluating the appropriateness of the ISO 9000 series standards with NIOSH-added requirements specific to respirators, or equivalent, to evaluate a manufacturer's quality system. NIOSH is also considering requirements for certification of auditors, and the oversight needed to ensure that audit quality is comparable to that which has been provided by NIOSH employees. Audits conducted by independent auditors would be used to complement NIOSH audits. The requirement for a pre-certification audit is also under evaluation. NIOSH intends to address the use of private sector quality auditors for the certification process in an Administrative/Quality Assurance module to be proposed in the near future.

C. Fee Schedule

Specifically, NIOSH sought comments on the following issues for updating the fee schedule to reflect the actual costs to maintain the program:

- Certification fee structure and calculation to recoup the cost of the certification process.
- NIOSH fee collection for manufacturing site and product audits.
- NIOSH fee collection for respirator complaint investigations.

1. Discussion of Comments Received

Eight commenters supported fair fee charges that accurately reflect the services received. These commenters stated that fees should be fair and equitable to NIOSH and the manufacturers. One of these commenters noted that excessive fees would be a deterrent to improving products, while another stated a willingness to pay more for faster approval. Two commenters recommended that collected fees be retained in the certification program to make it self-sustaining.

Five commenters did not think that NIOSH should recoup all costs of the program. One of these commenters felt there should not be charges for site and product audits. The other four argued against fees for product complaint investigations. One of them suggested there could be challenge procedures where the loser pays the investigative costs for a complaint. Another stated that the manufacturer should not be responsible for most complaints, because they are minor or frivolous. Another commenter believed that fees would be unfair because the manufacturer may not necessarily be at fault. The fifth commenter felt that NIOSH should bear the cost of complaint investigations because they are a NIOSH responsibility. Three of these commenters did indicate, however, that a fee may be appropriate if the basis for the complaint is

determined to be the manufacturer's fault.

Five commenters specifically endorsed a NIOSH fee to recoup the total cost for audits. One of these commenters stated that this would not be an additional expense for NIOSH or ISO-certified manufacturers if NIOSH accepted the results of ISO audits. Conversely, this commenter believed that NIOSH should conduct audits and charge fees to recoup their cost for manufacturers not ISO-certified. Another of these commenters suggested that the original fees that NIOSH charges for issuing a certification should include the costs of site and product audits.

One commenter stated that the fees should relate to all the tasks performed in the certification process. Another stated that the fee structure should include fees for each discrete, identifiable part of the process. A third commenter supported flat fees as the preferred fee structure. This commenter also stated that NIOSH should charge an hourly rate based on staff time and supply costs if flat rates can't be calculated. Two commenters suggested an annual maintenance fee based on the number of units produced or sales. One of these commenters further stated that an annual fee should be collected per model.

Two commenters suggested that fees should be reviewed and recalculated annually. Another commenter stated that the fees should be computed based on actual costs, and published for comment.

Several commenters recommended that collected fees be retained in the certification program to make it self-sustaining.

One commenter requested the establishment of fee accounts for withdrawal of fees when due.

2. Conclusions

The fees and fee structure for activities conducted in the certification program are currently based on the fee schedule contained in 42 CFR part 84. This fee schedule has not been updated since 1972. The costs of conducting a certification program have risen over the years, but these increased costs have not been reflected in certification charges. The fees charged for NIOSH services do not recover the costs to maintain the program.

NIOSH intends to update the current fee structure to offset the expenses and administrative costs of the program. NIOSH intends to update the current fee structure in an Administrative/Quality Assurance module to be proposed in the near future. For future updates in the fees, NIOSH may consider other fee structures to better cover the program costs.

D. Component Part Certification

Specifically, NIOSH sought comments on the following issues for evaluation and certification of respirator component parts:

- Authorization of manufacturers other than the original respirator manufacturer for replacement parts.
- Effectiveness of replacement parts, if alternate suppliers for replacement parts were allowed.
- Component-specific requirements of replacement parts, if alternate suppliers for replacement parts were allowed.
- Certification of respirator components in addition to, or instead of, complete respirators.
- Other certifying agencies or standards organizations that allow suppliers other than the original manufacturer to provide replacement parts for certified units.
- Monitoring of alternate suppliers, if suppliers other than the original manufacturer were permitted to provide replacement parts.
- Monitoring of replacement parts, if suppliers other than the original manufacturer were permitted to provide them.
- Interchangeability of parts by design specifications, if alternate suppliers for replacement parts were allowed.

1. Discussion of Comments Received

Three commenters endorsed the concept of component certification for the manufacture and sale of replacement parts by persons other than the respirator manufacturer. Two of these commenters stated that other standards or certifying organizations, including NFPA, allow third party replacement parts. One commenter stated that lower prices for respirators and disposable parts would result from standards that facilitate interchangeability of some parts. Two commenters stated that the replacement parts should be certified just as complete respirators, documenting equivalent form, fit and function of the original respirator. Component-specific requirements should be able to be covered in the general certification scheme, according to one commenter.

Most commenters did not favor the concept of component certification for the manufacture and sale of replacement parts by persons other than the respirator manufacturer. Nine commenters objected to allowing replacement parts from a manufacturer other than the respirator's original manufacturer. Respirator design restrictions to allow interchangeability of parts, copyright infringements and liability concerns were expressed as reasons for opposition.

Two commenters indicated that replacement parts by others should be permitted only if the manufacturer is in agreement. Four commenters voiced concerns of product liability of replacement parts by others. One commenter stated that the acceptable use of third party parts would encourage copyright infringements.

Six commenters believed there would be no way to verify original specifications are met with other manufacturers' parts. Therefore, they asserted, the certification program could not assure respirator system performance. Two commenters supported certification of complete respirators only. Two commenters stated that other standards, including SEI certification, Japanese, Korean, and Australian loosely-EN-based standards do not allow interchangeability of components.

Four commenters pointed out that interchangeability in Europe is allowed only for certain components. Two of these commenters asserted that the conformity required for interchangeability in Europe creates design restrictions. One commenter believed that developing component-based requirements would be horrendous. Another commenter reported the European experience to be that users don't utilize the option to obtain replacement parts from third parties. One commenter pointed to significant administrative expenses with testing and certification of replacement parts as another rationale for not adopting this concept.

Five commenters stated that NIOSH would need to monitor third party parts and suppliers the same as respirator manufacturers. Three commenters stated that allowing replacement parts by other than the respirator manufacturer would require testing to assure overall compliance of assembled respirator.

Some of the commenters opposing the concept recognized potential cost and program savings if a limited component certification program were developed. Three suggestions were made for components to be certified for use within the assembly of a single manufacturer's components, to make a complete respirator by the assembly of certified components. The certification for interchangeability of air lines and some air-supplied respirator parts were

also suggested as viable program options by two commenters.

2. Conclusions

The certification standards limit NIOSH to certify only complete respirators. Component parts are not evaluated independently. Any component part, or replacement part, certification program would require the development of component-specific requirements that ensure that the respirator continues to perform effectively.

No commenters raised safety or health concerns to support development of a component parts certification program. Only economic benefits were provided as reasons for support. Commenters raised seemingly valid safety and health, legal and technical concerns opposing component parts certification. Based on the comments received, NIOSH is not developing a component certification program at this time.

E. Product Auditing

Specifically, NIOSH sought comments on the following issues for product auditing of respirators:

- The maximum number of respirators per year, aside from problem investigations, that NIOSH should request from a manufacturer, at no charge to NIOSH.
- Acquisition of products for audit (i.e., by voucher, reimbursement, random selection by NIOSH at the manufacturer or distributor).
- Reimbursement of NIOSH costs for product audits.

1. Discussion of Comments Received

One commenter stated that there should be no charge for conducting product audits. This commenter stated that auditing costs should be included in the cost of government enforcement activities. Another commenter believed that, with the resources available to the government, the government should pay for all products it acquires. Five commenters indicated that fees should relate to the task, and that the total cost for any audit should be charged. One of these commenters thought that the original fees for a certification should include costs of site and product audits.

One commenter suggested that products for audit should be selected from the manufacturer's warehouse during site audits, as is done in other programs. A second commenter recommended a voucher system be used to acquire audit samples from distributors. This commenter stated that it was important that the manufacturer not be allowed to pre-screen audit samples to assure compliance.

2. Conclusions

NIOSH has historically purchased product audit samples from distributors. Although NIOSH occasionally requests audit samples from the manufacturer's inventory during site audits, products for audit are predominately purchased with appropriated funds. This severely limits the number and type of products that can be audited each year.

NIOSH is considering options to obtain appropriate numbers of product audit samples from manufacturers at no cost to NIOSH. NIOSH intends to address the acquisition of product audit samples in an Administrative/Quality Assurance module to be proposed in the near future.

F. Approval Duration

Specifically, NIOSH sought comments on the following issues for limiting the time duration or number of units for which a respirator certification would be valid:

- Time limits for the NIOSH certification to be valid.
- Conditions for renewing a NIOSH certification, if it were time-limited.
- Recommended time limits for a NIOSH certification and renewal, if it were time-limited.
- Notification requirements for changes in production status and the number of produced units when production is halted.
- Affect on purchasers and users if the certification of their respirator expires.
- Benefits to purchasers and users of an expired certification.
- Benefits to purchasers and users of knowing the number of respirators produced under a certification.

1. Discussion of Comments Received

Generally, comments were divided on the issue of time limits on an approval. Five commenters opposed time limits, while four commenters endorsed the concept.

Suggestions for a renewal process varied. One commenter suggested that annual renewal should be required. Another commenter pointed out that the National Fire Protection Association's standard for firefighter SCBA certification (NFPA 1981) requires recertification every 5 years. Yet another commenter stated that product approvals of this type are generally required to be requalified after a one to five year period. One commenter believed that a complete resubmittal from the manufacturer of the product should be required 9 years after certification, or the authority to manufacture and sell the product as NIOSH-certified would expire in the tenth year.

Commenters opposed to time or quantity limitations contended that certification expirations would cause undue user confusion and be overly burdensome on the manufacturers, and users would not benefit in knowing the population of specific models. One commenter pointed out that similar European requirements resulted in increased cost and obstructed sales. Several commenters also believed that production and sales levels are confidential to the manufacturer. Other commenters contended that such limitations were not needed because the evolution of products through technological advancements and approval schedule updates will limit the age of approvals that can remain active.

Three commenters suggested that NIOSH could require production change reports from the respirator manufacturers. A fourth commenter suggested that NIOSH could check the production status of approved respirators in conjunction with annual quality audits. Two commenters recommended that approvals be classified as Active, Inactive or Obsolete based on their production status. One of these commenters suggested inclusion of the production status in the NIOSH Certified Equipment List (CEL). Yet another commenter stated that users would be notified of an approval's expiration by removal from the equipment list.

2. Conclusions

NIOSH agrees with commenters who asserted that user notification of the status of NIOSH-certified respirators is important. NIOSH also agrees with commenters who believed that time or quantity limitations on certifications could create an added burden on manufacturers and NIOSH by creating added applications for recertification of products.

NIOSH is aware that manufacturers generally sell components individually that can be used in configurations covered under a number of certifications. Therefore, potentially little data exists to represent the number of respirators sold or in use under a specific approved design.

NIOSH has concluded that it would not be appropriate or beneficial to initiate time or quantity limitations on certifications at this time. The purpose of user notification on certifications could be served by receiving production status reports from respirator manufacturers to indicate if the respirator is currently being produced (active), no longer produced but units in

the field are supported with parts (inactive), or no longer in production or supported with replacement parts (obsolete).

The status listing of Active, Inactive, or Obsolete status is included in the NIOSH certified equipment list (CEL). In accordance with received comments, NIOSH is requesting the manufacturers to provide this production status information as soon as it becomes available, to update the CEL. NIOSH intends to address the reporting of production status information in an Administrative/Quality Assurance module to be proposed in the near future.

VII. Priority of Quality Assurance/ Administrative Modules

Based on the comments received, NIOSH intends to propose three Administrative/Quality Assurance modules. The intended subjects for these modules are:

A. Corrections and Existing Policies

1. Discussion of Comments Received

One commenter recommended that NIOSH publish technical amendments to 42 CFR part 84 prior to any other modules. Specifically, this commenter requested clarification of the 200 mg. filter loading levels for particulate filters used in pairs.

One commenter suggested that air purifying respirators with end of service life indicators (ESLI) should be certified for polyisocyanate catalyzed paints. Several commenters stated that workers were improperly protected because the adequate NIOSH-certified (supplied-air) respirators were not conducive to use. Estimates of 50,000 auto body shops with over 100,000 workers, with additional unnumbered workers such as law enforcement personnel and first response teams with accidental release of chemical agents and chemical warfare agents were given.

Air-purifying respirators can be certified with ESLI's in accordance with requirements published in the **Federal Register** on July 19, 1984 (49 FR 29270). That notice provided for the approval of air purifying respirators with either effective passive or active ESLI for use against gases and vapors with adequate warning properties or for use against gases and vapors with inadequate warning properties whenever there is a regulatory standard already permitting the use of air purifying respirators.

Two commenters suggested a module to address self contained self rescuers (SCSR) that are used in the mining industry. Both commenters urged development of a duration testing protocol using a metabolic simulator to replace human subject testing.

2. Conclusions

There are typographical errors in 42 CFR 84 to be corrected. There are also a number of existing program policies that have been developed since 1972 that are not included in the regulations. Policies affecting areas such as ESLI for air purifying respirators and service life plans for SCSR, need to be codified in the regulations as a single source for the respirator approval requirements.

NIOSH will publish a module to make corrections and incorporate all existing certification program policies into 42 CFR 84.

B. Upgrade of Quality Assurance Requirements and Fee Schedule

1. Discussion of Comments Received

As discussed previously in VI.B., no commenter opposed the use of private sector quality auditors in the certification program. Commenters also generally endorsed the use of ISO–9000 or similar quality assurance requirements. NIOSH acceptance of audits conducted by private sector auditors was also generally recommended by commenters.

As discussed previously in VI.C., the majority of commenters supported fees that reflect the costs of the certification program.

As discussed previously in VI.F., a number of commenters supported use of the NIOSH CEL to notify respirator users of the production status of approved respirators.

2. Conclusions

NIOSH intends to publish a module to address the use of independent quality auditors, respirator production status information and updated fees.

C. Use of Independent Testing Laboratories in the Certification Program and Restructured Fee Schedule

1. Discussion of Comments Received

As discussed previously in VI.A., a number of commenters expressed reservations about the ability of NIOSH to use private sector testing laboratories in the certification program. Several concerns, such as the availability of test procedures and the accreditation method, were presented.

As discussed previously in VI.C., some of the comments on fee revision recommended substantial changes to the fees structure. These recommendations included concepts such as: retention of the fees in the certification program; annual maintenance fees; and fees for complaint investigations.

2. Conclusions

NIOSH intends to publish a module to address the use of independent testing laboratories and a restructured fee schedule.

VIII. Continued Comments

As stated previously, NIOSH is requesting additional comments and information on content for the modules identified and prioritized in this notice. Comments for the need to prioritize other module topics are also welcomed. NIOSH will periodically review the information in the docket to assist in determining if a priority reassessment is needed. Comments should be mailed to the NIOSH Docket Office, Robert A. Taft Laboratories, M/S C34, 4676 Columbia Parkway, Cincinnati, Ohio 45226, telephone (513) 533–8450, fax (513) 533–8285. Comments may also be submitted by e-mail to: DMM2@CDC.GOV. E-mail attachments should be formatted as WordPerfect 4.2, 5.0, 5.1/5.2, 6.0/6.1, or ASCII files.

Dated: October 8, 1997.

Linda Rosenstock,

Director, National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).

[FR Doc. 97–27224 Filed 10–16–97; 8:45 am]

BILLING CODE 4163–19–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MM Docket No. 97–210, RM–9166]

Radio Broadcasting Services; Soldiers Grove, WI

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: This document requests comments on a petition filed by Lyle Robert Evans d/b/a Rural Radio Company proposing the allotment of Channel 290A to Soldiers Grove, Wisconsin, as that community's first local FM broadcast service. There is a site restriction 11.8 kilometers (7.3 miles) northeast of the community at coordinates 43–28–16 and 90–40–21.

DATES: Comments must be filed on or before November 24, 1997, and reply comments on or before December 9, 1997.

ADDRESSES: Federal Communications Commission, Washington, DC. 20554. In addition to filing comments with the FCC, interested parties should serve the petitioner, as follows: Lyle Robert Evans, d/b/a Rural Radio Company,

1296, Marian Lane, Green Bay, Wisconsin 54304.

FOR FURTHER INFORMATION CONTACT: Kathleen Scheuerle, Mass Media Bureau, (202) 418–2180.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Notice of Proposed Rule Making, MM Docket No. 97–210, adopted September 24, 1997, and released October 3, 1997. The full text of this Commission decision is available for inspection and copying during normal business hours in the Commission's Reference Center (Room 239), 1919 M Street, NW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractors, International Transcription Services, Inc., 1231 20th Street, NW., Washington, DC. 20036, (202) 857–3800, facsimile (202) 857–3805.

Provisions of the Regulatory Flexibility Act of l980 do not apply to this proceeding.

Members of the public should note that from the time a Notice of Proposed Rule Making is issued until the matter is no longer subject to Commission consideration or court review, all *ex parte* contacts are prohibited in Commission proceedings, such as this one, which involve channel allotments. See 47 CFR 1.1204(b) for rules governing permissible *ex parte* contact.

For information regarding proper filing procedures for comments, see 47 CFR 1.415 and 1.420.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

Federal Communications Commission.

John A. Karousos,

Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 97–27513 Filed 10–16–97; 8:45 am]

BILLING CODE 6712–01–F

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MM Docket No.97–209, RM–9152]

Radio Broadcasting Services; Coarsegold, CA

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: This document requests comments on a petition for rule making filed on behalf of Thomas L. Whitlock d.b.a. West Coast Wireless, seeking the allotment of FM Channel 233A to Coarsegold, California, as that community's first local aural transmission service. Coordinates for this proposal are 37–18–51 and 119–42–20.

DATES: Comments must be filed on or before November 24, 1997, and reply comments on or before December 9, 1997.

ADDRESSES: Secretary, Federal Communications Commission, Washington, DC 20554. In addition to filing comments with the FCC, interested parties should serve the petitioner's counsel, as follows: James A. Koerner, Esq., Baraff, Koerner & Olender, P.C., Three Bethesda Metro Center, Suite 640, Bethesda, MD 20814.

FOR FURTHER INFORMATION CONTACT: Nancy Joyner, Mass Media Bureau, (202) 418–2180.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Notice of Proposed Rule Making, MM Docket No. 97–209, adopted September 24, 1997, and released October 3, 1997. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC's Reference Center (Room 239), 1919 M Street, NW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractor, International Transcription Service, Inc., 1231 20th Street, NW., Washington, DC 20036, (202) 857–3800.

Provisions of the Regulatory Flexibility Act of l980 do not apply to this proceeding.

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For information regarding proper filing procedures for comments, See 47 CFR 1.415 and 1.420.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

Federal Communications Commission.

John A. Karousos,

Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 97–27512 Filed 10–16–97; 8:45 am]

BILLING CODE 6712–01–F

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MM Docket No. 97–136, RM–9083 and RM–9136]

Radio Broadcasting Services; Ironton, Malden and Salem, MO

AGENCY: Federal Communications Commission.

ACTION: Proposed rule; Order to Show Cause.

SUMMARY: In response to a counterproposal filed by B.B.C., Inc. and Dockins Communications, Inc., we have issued an Order to Show Cause to the Ultra-Sonic Broadcast Stations, Inc., licensee of Station KMMC, Channel 240A, Salem, Missouri. This document affords Station KMMC an opportunity to object to the proposed channel change but it does not afford an additional opportunity to comment on the merits of the proposal set forth in the Notice of Proposed Rule Making and Order to Show Cause or the proposal advanced in the counterproposal. *See* 62 FR 29090, May 29, 1997.

DATES: Comments must be filed on or before November 24, 1997.

ADDRESSES: Federal Communications Commission, Washington, DC. 20554.

FOR FURTHER INFORMATION CONTACT: Kathleen Scheuerle, Mass Media Bureau, (202) 418–2180.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Order to Show Cause, MM Docket No. 97–136, adopted September 24, 1997, and released October 3, 1997. The full text of this Commission decision is available for inspection and copying during normal business hours in the Commission's Reference Center (Room 239), 1919 M Street, NW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractors, International Transcription Services, Inc., 1231 20th Street, NW., Washington, DC. 20036, (202) 857–3800.

Provisions of the Regulatory Flexibility Act of l980 do not apply to this proceeding.

Members of the public should note that from the time a Notice of Proposed Rule Making is issued until the matter is no longer subject to Commission consideration or court review, all *ex parte* contacts are prohibited in Commission proceedings, such as this one, which involve channel allotments. See 47 CFR 1.1204(b) for rules governing permissible *ex parte* contact.

For information regarding proper filing procedures for comments, see 47 CFR 1.415 and 1.420.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

Federal Communications Commission.

John A. Karousos,

Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

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DEPARTMENT OF DEFENSE

48 CFR Parts 216, 245, and 252

[DFARS Case 97–D027]

Defense Federal Acquisition Regulation Supplement; Title to Government Property

AGENCY: Department of Defense (DoD).

ACTION: Proposed rule with request for comments.

SUMMARY: The Under Secretary of Defense, Acquisition and Technology, has requested the Director, Defense Procurement, to obtain public comment on Government property management policy changes intended to reduce the amount of Government-owned tooling and equipment in the possession of DoD contractors. This proposed rule solicits those comments and is structured as a deviation from the Federal Acquisition Regulation (FAR) Part 45 proposed rule on Government property (FAR Case 95–013) that was published in the **Federal Register** on June 2, 1997 (62 FR 30186). This proposed DFARS rule will be amended at a later date to incorporate changes resulting from public comments on the FAR Part 45 proposed rule.

DATES: Comments on the proposed rule should be submitted in writing to the address shown below on or before December 16, 1997 to be considered in the formulation of the final rule.

ADDRESSES: Interested parties should submit written comments to: Director, Defense Procurement, Deputy Director, Major Policy Initiatives, Attention: Ms. Angelena Moy, Room 3C128, 3060 Defense Pentagon, Washington, DC 20301–3060. Please cite DFARS Case 97–D027 in all correspondence related to this proposed rule. Address E-mail (Internet) comments to Moyac@acq.osd.mil.

FOR FURTHER INFORMATION CONTACT: Ms. Angelena Moy by phone at (703) 695–1097/8, by fax at (703) 695–7569, or at the E-mail address provided above. Please cite DFARS Case 97–D027.

SUPPLEMENTARY INFORMATION:

A. Background

The value of Government-owned equipment and tooling in the possession of DoD contractors increased substantially during the past decade although long-standing acquisition policy generally requires contractors to furnish the property needed to perform Government contracts. An Integrated Process Team, led by the Office of the Under Secretary of Defense, Industrial Affairs and Installations, has made recommendations intended to reverse this trend and reduce the amount of Government property in the possession of DoD contractors. These recommendations are:

1. Under cost-reimbursement contracts, DoD should cease taking title automatically to contractor acquired or fabricated equipment and tooling. DoD should have the right to take title to all special tooling and special test equipment for which costs are allocated to DoD contracts as direct costs, and items of equipment having an acquisition cost in excess of the DoD internal property accountability threshold (currently $2,500), the costs of which are allocated as direct costs to DoD contracts. This recommendation will reduce contract performance costs by removing low value equipment items from the property control, management, and disposal requirements in FAR Part 45. To implement this recommendation, language creating a deviation to the proposed FAR Part 45 rule appears in this proposed DFARS rule at 252.216–7002(c) and 252.245–7002(b)(2).

2. When a contractor that acquired or fabricated equipment, special tooling, or special test equipment to which DoD has taken title needs that equipment, special tooling, or special test equipment to perform follow-on contracts for the same items, DoD should furnish the equipment, special tooling, or special test equipment items to the contractor on an ''as is'' basis. To implement this recommendation, language creating a deviation to the proposed FAR Part 45 rule appears in this proposed DFARS rule at 252.245–7001(d)(2).

3. Property no longer needed for performance of a particular contract should be disposed of immediately if not needed for future procurements and placed under funded storage contracts if the future need is not within 60 days following the date the contractor identifies the property as no longer needed. This recommendation is intended to expedite property disposal and assure that contractors are paid for storing Government property. To implement this recommendation, language creating a deviation to the proposed FAR Part 45 rule appears in this proposed DFARS rule at 245.101–71.

B. Regulatory Flexibility Act

This proposed rule is not expected to have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act 5 U.S.C. 601, et seq., because the rule further reduces the economic impact on small entities from the estimated impact contained in the proposed rule under FAR Case 95–013, FAR Part 45, Government Property Rewrite, by reducing the administrative burden on contractors through reduction of the amount of Government property in the possession of contractors. The impact is not considered significant because the rule applies only to those small entities that request Government property to perform a contract or create Government property during contract performance, and contract prices compensate such contractors for their Government property management activities. An initial regulatory flexibility analysis has, therefore, has not been performed. Comments are invited from small businesses and other interested parties. Comments from small entities concerning the affected DFARS subparts also will be considered in accordance with 5 U.S.C. 610. Such comments should be submitted separately and should cite DFARS Case 97–D027 in correspondence.

C. Paperwork Reduction Act

This proposed rule reduces the amount of property that will become Government property under cost-reimbursement contracts. Therefore, the paperwork burden approved under Office of Management and Budget Clearance No. 9000–0151 for the proposed FAR rule published at 62 FR 30186 on June 2, 1997, is expected to be reduced.

List of Subjects in 48 CFR Parts 216, 245, and 252

Government procurement.

Michele P. Peterson,

Executive Editor, Defense Acquisition Regulations Council.

There, 48 CFR Parts 216, 245, and 252 are proposed to be amended as follows:

1. The authority citation for 48 CFR Parts 216, 245, and 252 continues to read as follows:

Auhority: 41 U.S.C. 421 and 48 CFR Chapter 1.

PART 216—TYPES OF CONTRACTS

2. Section 216.307 is added to read as follows:

216.307 Contract clauses.

(a)(1) Use the clause at 252.216–7002, allowable Cost and Payment, instead of the clause at FAR 52.216—7, Allowable Cost and Payment, in all cost-reimbursement contracts.

(2) Use the clause at 252.216–7002 with its Alternate I if the contract is a construction contract that contains the clause at FAR 52.232–27, Prompt Payment for Construction Contracts.

PART 245—GOVERNMENT PROPERTY

3. Section 245.101, 245.101–70, and 245.101–71 are added to read as follows:

245.101 Policy.

(d) Contractors are expected to have the means to perform DoD contracts. Furnish property to contractors only under the circumstances described in FAR 45.201 and only for performance of a specific contract or contracts.

245.101–70 Equipment, special tooling, and special test equipment.

Items of equipment, special tooling, or special test equipment that otherwise may be furnished to contractors under FAR 45.201 shall be furnished on an ''as is'' basis to the contractor that acquired or fabricated the items when that contractor needs the items for performance of follow-on contracts and the Government took title to the items under 252.245–7002, Right to Title—Equipment, Special Tooling, and Special Test Equipment.

245.101–71 Disposal and storage.

Immediately dispose of Government furnished property that a contractor has identified as no longer needed for contract performance except when there is a contractual requirement to furnish that property as Government furnished property under a follow-on contract. Contract for the property's storage when the property owner has a known future need for the property, a follow-on contract(s) has not been awarded, and the property will not be used within 60 days of the date upon which the contractor identified the property as no longer needed for contract performance.

4. Section 245.102 is added to read as follows:

245.102 Contract clauses.

(a)(1) Use the clause at 252.245–7001, Government Furnished Property, instead of the clause at FAR 52.245–1, Government Furnished Property (Fixed-Price and Labor-Hour Contracts), in all solicitations and contracts for supplies, services, or research and development if the Government anticipates furnishing property for performance of the contract.

(2) Use the clause at 252.245–7001 with its Alternate I in fixed-price competitive contracts or competitive labor-hour contracts.

(b)(i) Use the clause at 252.245–7002, Right to Title—Equipment, special Tooling, and Special Test Equipment, instead of the clause at FAR 52.245–2, Special Tooling and Special Test Equipment—Right to Title (Fixed-Price Contracts), in all solications and contracts.

(ii) Use the clause at 252.245–7002 with its Alternate I in cost-reimbursement or time-and-materials solicitations and contracts for basic or a applied research to be conducted by nonprofit organizations whose primary purpose is the conduct of scientific research on nonprofit in stitutions of higher education (see FAR 35.014).

(c)(i) Use the clause at 252.245–7003, Government Property Control, instead of the clause at FAR 52.245–3, Government Property Control, in all solicitations and contracts that include the clause at 252.245–7001.

(ii) Use the clause at 252.245–7003 with its Alternate I when the Government will maintain the Government's official property records (see FAR 45.302(b)).

(d) Use the clause at 252.245–7001, Government Furnished Property, instead of the clause at FAR 52.245–4, Government Property (Cost-Reimbursement and Time-and-Material Contracts), in all solicitations and contracts for supplies, services, or research and development if the Government anticipates furnishing property for performance of the contract.

245.505–14 [Removed]

5. Section 245.505–14 is removed.

PART 252—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

6. Section 252.216–7002 is added to read as follows:

252.216–7002 Allowable Cost and Payment.

As prescribed in 216.307(a)(1), used the following clause:

Allowable Cost and Payment (XXX 19XX)

(a) *Invoicing.* The Government shall make payments to the Contractor when requested as work progresses, but (except for small business concerns) not more often than once every 2 weeks, in amounts determined to be allowable by the Contracting Officer in accordance with Subpart 31.2 of the Federal Acquisition Regulation (FAR) in effect on the date of this contract and the terms of this contract. The Contractor may submit to an authorized representative of the Contracting Officer, in such form and reasonable detail as the representative may require, an invoice or voucher supported by a statement of the claimed allowable cost for performing this contract.

(b) *Reimbursing costs.*

(1) For the purpose of reimbursing allowable costs (except as provided in paragraph (b)(2) of this clause, with respect to pension, deferred profit sharing, and employee stock ownership plan contributions), the term ''costs'' includes only—

(i) Those recorded costs that, at the time of the request for reimbursement, the Contractor has paid by cash, check, or other form of actual payment for items or services purchased directly for the contract;

(ii) When the Contractor is not delinquent in paying costs of contract performance in the ordinary course of business, costs incurred, but not necessarily paid, for—

(A) Materials issued from the Contractor's inventory and placed in the production process for use on the contract;

(B) Direct labor;

(C) Direct travel;

(D) Other direct in-house costs; and

(E) Properly allocable and allowable indirect costs, as shown in the records maintained by the Contractor for purposes of obtaining reimbursement under Government contracts; and

(iii) The amount of progress and other payments that have been paid by cash, check, or other form of payment to the Contractor's subcontractors under similar cost standards.

(2) Contractor contributions to any pension or other post-retirement benefit, profit-sharing, or employee stock ownership plan funds that are paid quarterly or more often may be included in indirect costs for payment purposes; provided, that the Contractor pays the contribution to the fund within 30 days after the close of the period covered. Payments made 30 days or more after the close of a period shall not be included until the Contractor actually makes the payment. Accrued costs for such contributions that are paid less often than quarterly shall be excluded from indirect costs for payment purposes until the Contractor actually makes the payment.

(3) Notwithstanding the audit and adjustment of invoices or vouchers under paragraph (h) of this clause, allowable indirect costs under this contract shall be obtained by applying indirect cost rates established in accordance with paragraph (e) of this clause.

(4) Any statements in specifications or other documents incorporated in this contract by reference designating performance of services or furnishing of materials at the Contractor's expense or at no cost to the Government shall be disregarded for purposes of cost reimbursement under this clause.

(c) *Title.*

(1) Title to property acquired or fabricated by the Contractor for performance of this

contract, the costs of which are allocable to this contract as direct costs, shall vest in the Government. For property acquired or produced prior to execution of this contract, vestiture occurs upon execution of the contract. Otherwise, vestiture occurs when the property is or should have been allocable or properly chargeable to this contract under sound and generally accepted accounting principles and practices. Except as provided in the Right to Title—Equipment, Special Tooling, and Special Test Equipment clause of the contract, upon completion of deliveries under a contract for supplies or upon completion of effort required under a contract for services, the Contractor shall have title to all property acquired or fabricated for this contract that is not required to be delivered to the Government.

(2) Property to which the Government has obtained title under this clause is not ''Government furnished property.''

(d) *Small business concerns.* A small business concern may be paid more often than every 2 weeks and may invoice and be paid for recorded costs for items or services purchased directly for the contract, even though the concern has not yet paid for those items or services.

(e) *Final indirect cost rates.*

(1) Final annual indirect cost rates and the appropriate bases shall be established in accordance with Subpart 42.7 of the FAR in effect for the period covered by the indirect cost rate proposal.

(2) The Contractor shall, within 90 days after the expiration of each of its fiscal years, or by a later date approved by the Contracting Officer, submit to the cognizant Contracting Officer responsible for negotiating its final indirect cost rates and, if required by agency procedures, to the cognizant audit activity, proposed final indirect cost rates for that period and supporting cost data specifying the contract and/or subcontract to which the rates apply. The proposed rates shall be based on the Contractor's actual cost experience for that period. The appropriate Government representative and the Contractor shall establish the final indirect cost rates as promptly as practical after receipt of the Contractor's proposal.

(3) The Contractor and the appropriate Government representative shall execute a written understanding setting forth the final indirect cost rates. The understanding shall specify (i) the agreed-upon final annual indirect cost rates, (ii) the bases to which the rates apply, (iii) the periods for which the rates apply, (iv) any specific indirect cost items treated as direct costs in the settlement, and (v) the affected contract and/or subcontract, identifying any with advance agreements or special terms and the applicable rates. The understanding shall not change any monetary ceiling, contract obligation, or specific cost allowance or disallowance provided for in this contract. The understanding is incorporated into this contract upon execution.

(4) Within 120 days after settlement of the final indirect cost rates covering the year in which this contract is physically complete (or longer, if approved in writing by the Contracting Officer), the Contractor shall submit a completion invoice or voucher to reflect the settled amounts and rates.

(5) Failure by the parties to agree on a final annual indirect cost rate shall be a dispute within the meaning of the Disputes clause of this contract.

(f) *Billing rates.* Until final annual indirect cost rates are established for any period, the Government shall reimburse the Contractor at billing rates established by the Contracting Officer or by an authorized representative (the cognizant auditor), subject to adjustment when the final rates are established. These billing rates—(1) Shall be the anticipated final rates; and (2) May be prospectively or retroactively revised by mutual agreement, at either party's request, to prevent substantial overpayment or underpayment.

(g) *Quick-closeout procedures.* Quick-closeout procedures are applicable when the conditions in FAR 42.708(a) are satisfied.

(h) *Audit.* At any time or times before final payment, the Contracting Officer may have the Contractor's invoices or vouchers and statements of cost audited. Any payment may be reduced by amounts found by the Contracting Officer not to constitute allowable costs or adjusted for prior overpayments or underpayments.

(i) *Final payment.*

(1) Upon approval of a completion invoice or voucher submitted by the Contractor in accordance with paragraph (e)(4) of this clause, and upon the Contractor's compliance with all terms of this contract, the Government shall promptly pay any balance of allowable costs and that part of the fee (if any) not previously paid.

(2) The Contractor shall pay to the Government any refunds, rebates, credits, or other amounts (including interest, if any) accruing to or received by the Contractor or any assignee under this contract, to the extent that those amounts are properly allocable to costs for which the Contractor has been reimbursed by the Government. Reasonable expenses incurred by the Contractor for securing refunds, rebates, credits, or other amounts shall be allowable costs if approved by the Contracting Officer. Before final payment under this contract, the Contractor and each assignee whose assignment is in effect at the time of final payment shall execute and deliver—

(i) An assignment to the Government, in form and substance satisfactory to the Contracting Officer, of refunds, rebates, credits, or other amounts (including interest, if any) properly allocable to costs for which the Contractor has been reimbursed by the Government under this contract; and

(ii) A release discharging the Government, its officers, agents, and employees from all liabilities, obligations, and claims arising out of or under this contract, except—

(A) Specified claims stated in exact amounts, or in estimated amounts when the exact amounts are not known;

(B) Claims (including reasonable incidental expenses) based upon liabilities of the Contractor to third parties arising out of the performance of this contract; provided, that the claims are not known to the Contractor on the date of the execution of the release, and that the Contractor gives notice of the claims in writing to the Contracting Officer within 6 years following the release date or notice of final payment date, whichever is earlier; and

(C) Claims for reimbursement of costs, including reasonable incidental expenses, incurred by the Contractor under the patent clauses of this contract, excluding, however, any expenses arising from the Contractor's indemnification of the Government against patent liability.

(End of clause)

ALTERNATE I (XXX 19XX). As prescribed in 216.307(a)(2), substitute the following paragraph (b)(1)(iii) for paragraph (b)(1)(iii) of the basic clause:

(iii) The amount of progress and other payments to the Contractor's subcontractors that either have been paid, or that the Contractor is required to pay pursuant to the Prompt Payment for Construction Contracts clause of this contract. Payments shall be made by cash, check, or other form of payment to the Contractor's subcontractors under similar cost standards.

7. Section 252.245–7001 is revised to read as follows:

252.245–7001 Government Furnished Property.

As prescribed in 245.102(a) (1) and (d), use the following clause:

Government Furnished Property (XXX 19XX)

(a) *Definitions.*

The terms defined in the Right to Title—Equipment, Special Tooling, and Special Test Equipment clause of this contract have the same meaning in this clause.

(b) *Property furnished for performance of this contract.*

(1) The Government furnished property identified in this contract may be used for performance of the contract on a rent-free basis. The Contractor shall not use such property on any other Government contracts or for commercial purposes without the Contracting Officer's prior approval. Unless otherwise permitted by law, commercial use shall be on a rental basis. The terms and conditions of the Rental Charges for Commercial Use clause of this contract shall apply to each rental.

(2) The Contractor shall not improve or make structural alterations to real property owned or leased by the Government and made available for performance of this contract unless expressly authorized to do so in writing by the Contracting Officer. Title to such improvements or alterations shall vest in the Government if the property is accountable under this contract or will be determined by the terms of the contract under which the real property is accountable.

(3) The Government retains title to Government furnished property including Government furnished property that is incorporated into or attached to any property it does not own. Government furnished property does not become a fixture or lose its identity as personal property by being attached to real property.

(4) The Government shall, when requested by the Contractor, provide information reasonably required for the property's intended use to the extent the Government has the right to release or disclose the information.

(5) If the Contractor commingles Contractor acquired or fabricated material with

Government furnished material, the provisions of paragraph (c) of this clause regarding suitability for intended use shall not apply to the commingled Government furnished material. Notwithstanding any other provision of this contract, the Contractor shall be responsible for any failure to comply with contract requirements attributable to material that was commingled.

(c) *Suitability for intended use.*

The contract delivery or performance dates are based upon the expectation that Government furnished property will be suitable for its intended use, except property furnished ''as is'' (see paragraph (d) of this clause), and delivered to the Contractor at the times stated in the contract or, if not so stated, in sufficient time to enable the Contractor to meet the contract's delivery or performance dates.

(1) The Contractor shall notify the Contracting Officer promptly following receipt of Government furnished property that is not suitable for its intended use and take corrective action or dispose of the property as directed by the Contracting Officer. The contract shall be equitably adjusted in accordance with paragraph (g) of this clause.

(2) The Contractor may request an equitable adjustment when Government furnished property is not delivered to the Contractor by the required time and such untimely delivery has affected contract performance. Any equitable adjustment shall be made in accordance with paragraph (g) of this clause.

(d) *Property furnished as is.*

(1) Offerors and the Contractor are responsible for assuring that Government property made available on an ''as is'' basis is suitable for the offerors' or Contractor's purposes. Such property is furnished f.o.b. at the location specified in the solicitation or contract. Any cost incurred by the Contractor to transport, install, modify, repair, or otherwise make such property suitable for the Contractor's intended use shall not result in an increase in price or fee. Modifications to property furnished ''as is'' require the Contracting Officer's prior written approval.

(2) Equipment, special tooling, or special test equipment is furnished ''as is'' for performance of this contract if the Contractor acquired or fabricated, and the Government took title to, such items under this or a prior contract.

(3) The Government makes no warranty whatsoever with respect to property furnished ''as is'' except that the property will be in the same condition when placed at the specified f.o.b. location as when inspected by the Contractor or, if not inspected by the Contractor, as of the last date identified in the solicitation or contract for Contractor inspection. The Contractor is responsible for verifying that the property's condition has not changed during that period. If the Contractor determines the property's condition has changed and such change will adversely affect the Contractor, the Contractor shall immediately notify the Contracting Officer and identify the changed condition. If the Contracting Officer concurs that the property's condition has changed, the Contracting Officer may restore the property or substitute other Government property at no change in price or fee; permit the Contractor to restore the property subject to an equitable adjustment; or decline to furnish the property subject to an equitable adjustment. The foregoing provisions for adjustment are the exclusive remedies available to the Contractor. The Government has no liability for changes in the property's condition discovered after removal from the specified f.o.b. location.

(4) Repairs to or modifications of property furnished ''as is'' do not affect the Government's title to such property.

(e) *Changes in Government furnished property.*

(1) The Contracting Officer may increase, decrease, or substitute other Government property for the property furnished or to be furnished for performance of this contract or require use of Government furnished property in lieu of Contractor property.

(2) Except as provided in paragraph (e)(4) of this clause, any increase in the amount of property furnished for performance of this contract shall result in an equitable reduction in price or fee, and an appropriate adjustment of the contract delivery or performance dates.

(3) The Contractor may request an equitable adjustment in accordance with paragraph (g) of this clause for a decrease in or substitution for the property identified in the contract or withdrawal of authority to use property accountable under another contract in performance of this contract, provided such decrease, substitution, or withdrawal increases the costs of contract performance.

(4) If the Contracting Officer directs the Contractor to use Government furnished property in lieu of Contractor property in performance of this contract, any adjustment to the contract shall be made in accordance with the Changes clause of this contract.

(f) *Limited risk of loss.*

(1) The Contractor's liability for loss, theft, or destruction of, or damage to, Government furnished property accountable under this contract shall be limited if the Contractor maintains a property control system that satisfies the requirements of the Government Property Control clause of this contract (hereinafter referred to as an approved system).

(2) When the Contractor maintains an approved system, the Contractor shall not be liable for loss, theft, or destruction of, or damage to, Government property accountable under this contract except loss, theft, destruction, or damage for which the Contractor is expressly responsible under the terms of this contract or loss, theft, destruction, or damage that results from—

(i) A risk expressly required to be insured under this contract but only to the extent of the insurance required to be purchased and maintained, or to the extent of insurance actually purchased and maintained, whichever is greater;

(ii) A risk that is in fact covered by insurance or for which the Contractor is otherwise reimbursed, but only to the extent of such insurance or reimbursement; or

(iii) Willful misconduct or lack of good faith on the part of the Contractor's managerial personnel.

(3) Following notice from the Government's property administrator to one of the Contractor's managerial personnel that the Contractor's or a subcontractor's property control system is not in compliance with the requirements of the Government Property Control clause of this contract, the Contractor's failure to correct its system or to have a subcontractor's system corrected within the dates specified by the Government's property administrator, or such other mutually agreed dates, shall be considered willful misconduct or lack of good faith on the part of the Contractor's managerial personnel. The Contractor shall be liable for any loss, theft, or destruction of, or damage to, the Government furnished property accountable under this contract except such loss, theft, destruction, or damage that the Contractor can establish by clear and convincing evidence—

(i) Did not result from the Contractor's failure to maintain an approved system; or

(ii) Occurred while an approved system was maintained by the Contractor.

(4) Except as provided in paragraphs (f)(3)(i) and (ii) of this clause, the Contractor shall be liable for loss, theft, or destruction of, or damage to, Government furnished property accountable under this contract immediately upon notice by certified mail that the Government has withdrawn approval of the Contractor's property control system.

(5) The Contractor is not liable for Government furnished property properly consumed in performing this contract. The Contractor shall have no liability for loss, theft, or destruction of, or damage to, Government property furnished for performance of services entirely on real property owned or leased by the Government when the Contractor does not control the use of, or access to, such property.

(6) The Contractor's transfer of Government furnished property to the possession and control of a subcontractor, does not affect the Contractor's liability for loss, theft, or destruction of, or damage to, that property.

(7) Except as provided in paragraph (f)(8) of this clause, the Contractor shall notify the Government's property administrator in writing promptly following the loss, theft, or destruction of, or damage to, Government furnished property. Such notice shall identify—

(i) Lost, stolen, destroyed, or damaged Government property by description, contract number, national stock number (if known), and either part number or identification number;

(ii) The date a loss or theft was discovered or damage or destruction occurred and, if known, the circumstances;

(iii) Each property item's acquisition cost;

(iv) The contracts affected;

(v) All known interests in commingled property of which Government furnished property is a part; and

(vi) The insurance, if any, covering any part of or interest in such commingled property.

(8) The Contractor is not required to provide notice of loss, theft, or destruction of, or damage to, low value property that the Contractor does not need for continued performance of this contract until contract

completion or termination. Such notice shall include the information required by paragraph (f)(7) of this clause.

(9) The Contractor shall take all reasonable action to protect damaged Government furnished property from further damage and to physically separate such property from all other property.

(10) The Contractor shall repair, renovate, or take such other action with respect to lost, stolen, damaged, or destroyed Government furnished property as the Contracting Officer directs and adjust the property records accordingly. When such repair, renovation, or action is not the Contractor's responsibility under this contract, the Contractor shall be entitled to an equitable adjustment in accordance with paragraph (g) of this clause. Contractor-responsible repairs to, or replacement of, Government furnished property shall be accomplished at no change price or fee.

(11) The Contractor shall not include in the price or fee of this contract any charge or reserve for insurance (including any self-insurance fund or reserve) covering loss, theft, or destruction of, or damage to, Government furnished property except to the extent the Government might have expressly required the Contractor to carry such insurance under another provision of this contract.

(12) If the Contractor is reimbursed or otherwise compensated for any loss, theft, or destruction of, or damage to, Government furnished property, the Contractor shall use the proceeds to repair, renovate, or replace such property or equitably reimburse the Government, as directed by the Contracting Officer, and adjust the property records accordingly.

(13) The Contractor shall do nothing to prejudice the Government's rights to recover against third parties for any loss, theft, or destruction of, or damage to, Government furnished property. When requested by the Contracting Officer, the Contractor shall, at Government expense, furnish to the Government all reasonable assistance and cooperation (including the prosecution of suit and the execution of instruments of assignment in favor of the Government) in obtaining recovery.

(g) *Equitable adjustments.* (1) Equitable adjustments shall be the Contractor's exclusive remedy for Government actions under this clause and shall be made in accordance with the procedures of the Changes clause of this contract. The Government shall not be liable to suit for breach of contract for—

(i) Any delay in delivery of Government furnished property;

(ii) Delivery of Government furnished property in a condition not suitable for its intended use;

(iii) An increase or decrease in, or substitution of, Government furnished property; or

(iv) Failure to repair or replace Government furnished property when the Government is responsible for repair or replacement.

(2) An equitable adjustment for Government furnished property that is not in a condition suitable for intended use or the withdrawal or substitution of Government furnished property may include an amount for the restoration and rehabilitation of the Contractor's premises caused by such condition, withdrawal, or substitution.

(h) *Maintenance responsibilities.* (1) The Contractor is responsible for the maintenance of Government furnished property accountable under this contract, including such property stored at a Contractor managed site. The Contractor shall perform all maintenance, including preventive maintenance, necessary to assure that Government furnished property remains suitable for its intended use unless the Contracting Officer specifically relieves the Contractor of its maintenance responsibility for a particular item or class of items. If routine and preventive maintenance are not sufficient to sustain a property item's suitability for intended use, the Contractor shall notify the Contracting Officer promptly and request direction regarding repair or replacement.

(2) The Contractor shall notify promptly the Government's property administrator of the need for any replacement of, or major repair or rehabilitation to, Government furnished property discovered during its maintenance activities and shall not effect such repair, replacement, or rehabilitation unless authorized to do so by the Contracting Officer.

(i) *Return of Government furnished property.* If this contract requires Government furnished property to be returned directly to the Government and not entered into the property disposal process—

(1) The Contractor shall notify the Contract Administration Office of its intent to return such property at least 10 working days prior to return. Notices shall identify the contracts under which the items are accountable and provide each item's name, description, and national stock number, if known, or part number or identification number.

(2) The property shall be returned to the Government in a condition suitable for its intended use except—

(i) Lost, stolen, or destroyed property that the Government has determined will not be replaced;

(ii) Damaged property that the Government has determined will not be repaired;

(iii) Property consumed in performance of this contract;

(iv) Property attached to, incorporated into, or delivered with, a deliverable end item; or

(v) Property furnished ''as is'' shall be returned in equal or better condition than when furnished to the Contractor.

(j) *Disposal of Government furnished property.*—(1) *Inventory disposal schedules.* Except as provided in paragraph (i) or (j)(2) of this clause, the Contractor shall identify Government furnished property no longer required for performance of this contract using Standard Form 1428, Inventory Disposal Schedule. Unless the plant clearance officer has agreed to a different submission basis, or the contract requires inventory disposal schedules to be submitted electronically, the Contractor shall prepare separate inventory disposal schedules for: special test equipment with general purpose components; special test equipment that does not contain general purpose components; printing equipment; automatic data processing equipment; nonnuclear hazardous materials; and nuclear materials. Property with the same description, condition code, and reporting location may be grouped in a single line item. Special test equipment shall be described in sufficient detail to permit an understanding of the special test equipment's intended use. The Contractor may annotate the schedule to identify test equipment the Contractor wishes to purchase from the Government or general purpose components thereof the Contractor wishes to purchase or use in the performance of other Government contracts.

(2) *Scrap Lists.* Contractors that have Government approved scrap procedures may prepare scrap lists (provided such lists are consistent with the approved scrap procedures) in lieu of inventory disposal schedules except for scrap that—

(i) Requires demilitarization;

(ii) Is a classified item;

(iii) Is generated from classified items;

(iv) Contains hazardous materials; or

(v) Is dangerous to the public health, safety, or welfare.

(3) *Corrections.* If the plant clearance officer finds that property identified on an inventory disposal schedule or scrap list is not accountable under this contract or is not in the quantity or condition indicated on the inventory disposal schedule or scrap list, the plant clearance officer may require the Contractor to correct the inventory disposal schedule or scrap list, may reject such schedules or lists at any time, or may require submission of an inventory control schedule in lieu of a scrap list.

(4) *Submission requirements.* Inventory disposal schedules or scrap lists shall be submitted to the plant clearance officer for approval no later than—

(i) 30 days following the Contractor's determination that a Government furnished property item is no longer required for performance of the contract;

(ii) 60 days following completion of contract deliveries or performance or such longer period as may be approved by the plant clearance officer; or

(iii) 120 days following contract termination in whole or in part or such longer period as may be approved by the Contracting Officer.

(5) *Inventory schedule adjustments.* The Contractor shall provide the plant clearance officer at least 10 working days advance written notice of its intent to remove a Government furnished property item, including an item identified as scrap, from an approved inventory disposal schedule. Unless the plant clearance officer objects to the intended schedule adjustment within the notice period, the Contractor may make the adjustment upon expiration of the notice period.

(6) *Storage.* The Contractor shall store the Government furnished property identified in an inventory disposal schedule pending receipt of disposal instructions. If the Government fails to provide disposal instructions within 120 days following receipt of an acceptable inventory disposal schedule, the Contractor might be entitled to

an equitable adjustment for costs incurred to store such property on or after the 121st day following receipt of an acceptable schedule.

(7) *Disposal.* Except as provided in paragraph (j)(7)(i) of this clause, Government furnished property shall not be disposed of until the Contractor has been authorized to do so by the plant clearance officer.

(i) If the Government does not provide disposition instructions to the Contractor within 60 days following receipt of an acceptable scrap list, the Contractor may dispose of the listed scrap.

(ii) The Contractor shall prepare for shipment, deliver f.o.b. origin, or dispose of Government furnished property as directed by the plant clearance officer. The Contractor shall remove and destroy any markings identifying the property as Government property when the plant clearance officer directs disposal by sale or donation, notifies the Contractor that the Government has abandoned the property, or directs the Contractor to scrap the property.

(iii) The net proceeds from a disposal action of scrapped Government furnished property shall be credited to the contract under which the Government furnished property was accountable or, when scrapped Government furnished property cannot be segregated from other scrap, to an appropriate overhead account. The Contractor shall credit the net proceeds or other disposal actions in accordance with instructions provided by the plant clearance officer.

(iv) The Contracting Officer may require the Contractor to demilitarize the property prior to shipment or disposal. Any adjustment in contract price incident to the Contracting Officer's direction to demilitarize Government furnished property shall be made in accordance with paragraph (g) of this clause.

(8) *Contractor removal of property.* The Contractor must obtain the plant clearance officer's approval to remove Government furnished property from its premises prior to receipt of final disposition instructions. If approval is granted, the Contractor shall transport and store the property at no change in price or fee. The storage facility must be appropriate for assuring the property's physical safety and suitability for use. Approval does not relieve the Contractor of liability for loss, theft, or destruction of, or damage to, such property.

(9) *Subcontractor inventory disposal schedules.* When the Contractor permits a subcontractor or supplier to use, at a subcontractor or supplier managed site, Government property furnished to the Contractor for performance of this contract, the Contractor shall require the subcontractor or supplier to submit inventory disposal schedules or scrap lists to the Contractor in sufficient time for the Contractor to comply with the requirements of paragraph (j)(4) of this clause.

(k) *Abandonment and restoration of Contractor's premises.* (1) The Government shall not abandon Government furnished property that is or contains a hazardous material at a Contractor-owned location without the Contractor's written concurrence. The Contractor may request an equitable adjustment incident to such agreement.

(2) The Government, upon notice to the Contractor, may abandon any nonhazardous Government property in place at which time all obligations of the Government regarding such abandoned property shall cease. The Government has no obligation to restore or rehabilitate the Contractor's premises under any circumstances and, except as provided in paragraphs (g)(2) and (k)(1) of this clause, has no liability for such restoration or rehabilitation.

(l) *Overseas contracts.* In a contract performed outside the United States, its territories, or possessions, the words ''Government'' and ''Government furnished,'' as used in this clause, mean ''United States Government'' and ''United States Government furnished,'' respectively.

(End of clause)

Alternate I (XXX 19XX). As prescribed in 245.102(a)(2), substitute the following paragraph (f) for paragraph (f) of the basic clause:

(f) *Risk of loss.*

(1) Except as provided in paragraph (f)(3) of this clause, the Contractor is liable for any loss, theft, or destruction of, or damage to, Government furnished property accountable under this contract.

(2) Contractor-responsible repairs to, or replacements of, Government furnished property shall be accomplished at no change in price or fee.

(3) The Contractor is not liable for—

(i) Government furnished property properly consumed in performing this contract; or

(ii) Loss, theft, or destruction of, or damage to, Government furnished property when the Contractor is providing services performed entirely on real property owned or leased by the Government and the Contractor does not control the use of, or access to, the Government furnished property.

(4) Except as provided in paragraph (f)(5) of this clause, the Contractor shall notify the Government's property administrator in writing promptly following the loss, theft, or destruction of, or damage to, Government furnished property. Such notice shall identify—

(i) Lost, stolen, destroyed, or damaged Government property by description, contract number, national stock number (if known), and either part number or identification number;

(ii) The date a loss or theft was discovered or damage or destruction occurred and, if known, the circumstances;

(iii) Each property item's acquisition cost;

(iv) The contracts affected;

(v) All known interests in commingled property of which the Government property is a part; and

(vi) The insurance, if any, covering any part of or interest in such commingled property.

(5) The Contractor is not required to provide notice of loss, theft, or destruction of, or damage to, low value property that the Contractor does not need for continued performance of this contract until contract completion or termination. Such notice shall include the contract number and each such property item's acquisition cost, description, national stock number (if known), and either its part number or identification number.

(6) The Contractor shall take all reasonable action to protect damaged Government furnished property from further damage and to physically separate such property from all other property.

(7) The Contracting Officer may replace, direct the Contractor to repair or replace, or direct the Contractor to take other appropriate action regarding lost, stolen, damaged, or destroyed Government furnished property for which the Government has specifically assumed such risks in this contract. When lost, damaged, stolen, or destroyed Government furnished property is replaced by the Government or the Contractor, the replacement property shall be entered into the property control system as a Government furnished property item. Any equitable adjustment incident to such direction shall be determined in accordance with paragraph (g) of this clause.

8. Section 252.245–7002 is added to read as follows:

252.245–7002 Right to Title—Equipment, Special Tooling, and Special Test Equipment.

As prescribed in 245.102(b)(i), use the following clause:

Right to Title—Equipment, Special Tooling, and Special Test Equipment (XXX 19XX)

(a) *Definitions.*

As used in this clause—

''Contractor's managerial personnel'' means the Contractor's directors, officers, and any of the Contractor's managers, superintendents, or equivalent representatives who have supervision or direction of all or substantially all of the Contractor's business; or operations at a site connected with performance of this contract.

''Equipment'' means items whose use is not limited to, or with only minor modification would be limited to, the development, production, or maintenance of a particular item or the performance of a particular service. The term includes, but is not limited to, automatic data processing equipment, office equipment, construction equipment, hand tools, machine tools (other than special tooling), test equipment (other than special test equipment or components thereof), furniture, and vehicles.

''Government property'' means property the Government owns or leases.

''Government furnished property'' means property provided by the Government to a contractor for performance of a contract.

''Low value property'' means equipment, special tooling, or special test equipment that has an acquisition cost of $2,500 or less and is not sensitive property.

''Material'' means property to be consumed or expended to perform a service or produce a deliverable end item and property incorporated into or attached to an end item. The term includes assemblies, components, parts, raw and processed materials, and supplies that may be consumed in normal use in performing a contract. It does not include equipment, real property, special test equipment, special tooling, or unique Federal property.

''Nonprofit organization'' means a business entity organized and operated exclusively for

charitable, scientific, or educational purposes, the net earnings of which do not inure to the benefit of any private shareholder or individual, that is exempt from Federal income taxation under section 501 of the Internal Revenue Code and does not conduct a substantial portion of its activities carrying on propaganda or otherwise attempting to influence legislation or participating in any political campaign on behalf of any candidate for public office.

''Personal property'' means property of any kind or interest in it except real property, battleships, cruisers, aircraft carriers, destroyers, submarines, and records of the Government.

''Plant clearance officer'' means a person appointed to perform plant clearance functions.

''Precious metals'' means silver, gold, platinum, palladium, iridium, osmium, rhodium, and ruthenium.

''Preventive maintenance'' means regularly scheduled maintenance performed to sustain suitability for intended use and detect and correct minor deficiencies before they result in serious consequences.

''Property'' means real and personal property.

''Property administrator'' means a person appointed to perform Government property administration.

''Real property'' means land and rights in land, ground improvements, utility distribution systems, and buildings and other structures. It does not include foundations and other work necessary for installing special tooling, special test equipment, or equipment.

''Scrap'' means personal property that has no value except its basic metallic, mineral, or organic content.

''Sensitive property'' means property potentially dangerous to the public safety or security if stolen, lost, or misplaced, or that must be subject to exceptional physical security, protection, control, and accountability such as classified property, weapons, ammunition, explosives, controlled substances, radioactive materials, hazardous materials or wastes, or precious metals.

''Special test equipment'' means a test unit or units designed, fabricated, or modified to accomplish special purpose testing, groupings of such items, that are interconnected and interdependent so as to become a new functional entity.,

''Special tooling'' means items, such as jigs, dies, fixtures, molds, patterns, taps, gauges, or other equipment and manufacturing aids, that are of such a specialized nature that without substantial modification or alteration their use is limited to the development, production, repair, or maintenance of particular supplies or components thereof, or to the performance of particular services.

''Unique Federal property'' means Government owned personal property, or components thereof, that is specially designed to perform or support the mission of one or more Federal agencies and is not available to the public.

''Work in process'' means bench stock materials, complete or incomplete fabricated parts, subassemblies, assemblies, and similar items that are created during production of deliverable end items or are required to construct special tooling or special test equipment needed to produce deliverable end items.

(b) *Right to title.—(1) Fixed-price contracts.* The Government has the right, at no change in contract price, to take title to each special tooling or special test equipment item acquired or fabricated by the Contractor that is not required to be delivered under this contract if the item's cost is allocable to this contract as a direct cost.

(2) *Cost-reimbursement contracts.* The Government has the right, at no change in cost or fee, to take title to each—

(i) Special tooling or special test equipment item acquired or fabricated by the Contractor that is not required to be delivered under this contract if the item's cost is allocable to this contract as a direct cost.

(ii) Item of equipment acquired or fabricated by the Contractor that is not required to be delivered under this contract if the item's cost is greater than $2,500 and is allocable to this contract as a direct cost.

(3) *Expiration.* The Government's rights in paragraphs (b)(1) and (b)(2) of this clause end upon expiration of the time period in paragraph (e) of this clause.

(c) *Reports.* (1) The Contractor shall submit to the Contracting Officer a report identifying right to title items as soon as practicable during contract performance but not later than the earlier of—

(i) 90 days prior to completion of scheduled deliveries (other than technical data) under this contract; or

(ii) 30 days following the Contractor's determination that a right to title item is no longer required for contract performance.

For each right to title item or groups of identical items, the reports shall identify the item's or group's—

(i) Nomenclature;

(ii) Quantity;

(iii) Acquisition cost;

(iv) Contract number;

(v) Part number(s) made or tested; and

(vi) Identification number.

(d) *Storage.* The Contractor shall store each right to title item identified in a report required by paragraph (c) of this clause at no increase in fee or price. The Contractor's storage obligations for a right to title item end when the Government notifies the Contractor that it has taken title to that item or upon expiration of the Government notice period. Items shall be stored in a manner sufficient to preserve capability and provide protection from damage. If the Government requires items to be stored subsequent to the Government's assumption of title, the Contractor might be entitled to an equitable adjustment as provided in paragraph (g) of this clause.

(e) *Assumption of title.* (1) The Government must notify the Contractor that it is taking title to an item or items within 120 days, or such other period mutually agreed upon, following receipt of a report required by paragraph (c) of this clause or other written notice from the Contractor identifying the item or items as no longer required for performance of this contract.

(2) The Government's notice shall be in writing, shall identify the item(s), and may, in any combination—

(i) Provide packing, packaging, marking, and shipping instructions;

(ii) Direct the Contractor to prepare the property for storage at the Contractor's facility or a Government facility; or

(iii) Provide instructions when accountability is to be transferred to another contract.

(3) The Contractor's storage obligations are not diminished if the Government notice period, or any extension thereof, extends beyond the date contract deliveries are completed.

(f) *Marking.* The Contractor shall legibly and conspicuously mark property to which the Government has taken title under this contract with the phrase ''U.S. Government Property'' (or a similar phrase that conveys Government ownership), as soon as practicable following the Government's assumption of title.

(g) *Price adjustment.* The cost and fee of a cost-reimbursement contract or the price of a fixed-price contract may be equitably adjusted for costs incurred by the Contractor to store, prepare for storage, package, pack, or mark for shipment, the equipment, special tooling, or special test equipment to which the Government has taken title. Any adjustment shall be made in accordance with the procedures of the Changes clause of this contract and only to the extent the Contracting Officer's actions under paragraph (e) of this clause required the Contractor to incur costs that it would not have incurred under customary commercial practices.

(h) *Risk of loss.* The Contractor is responsible for any loss, theft, or destruction of, or damage to, right to title items during the period commencing upon the Government's delivery of the notice required by paragraph (e) of this clause and ending upon placement aboard a carrier's conveyance (f.o.b. origin) or delivery at the specified f.o.b. destination point.

(i) *Flow down.* The Contractor shall insert this or a substantially similar clause in all contracts and similar instruments with its first-tier subcontractors or suppliers, other than subcontractors or suppliers of commercial items, that will fabricate or acquire equipment, special tooling, or special test equipment for performance of this contract.

(End of clause)

ALTERNATE I (XXX 19XX). As prescribed in 245.102(b)(ii), substitute the following paragraph (b) for paragraph (b) of the basic clause:

(b) *Right to title*—(1) *General.* The Government has the right, at no change in cost or fee, to take title to each—

(i) Special tooling or special test equipment item acquired or fabricated by the Contractor that is not required to be delivered under this contract if the item's cost is allocable to this contract as a direct cost.

(ii) Item of equipment acquired or fabricated by the Contractor that is not required to be delivered under this contract if the item's cost is greater than $2,500 and is allocable to this contract as a direct cost.

(2) *Expiration.* Except as provided in paragraph (b)(3) of this clause, the

Government's rights in paragraphs (b)(1)(i) and (b)(1)(ii) of this clause end upon expiration of the time period in paragraph (e) of this clause.

(3) *Relinquishment of rights.* Prior to purchasing equipment, special tooling, or special test equipment with Government funds provided for the conduct of basic or applied research, nonprofit organizations whose primary purpose is the conduct of scientific research or nonprofit institutions of higher education (see FAR 35.014) may request the Contracting Officer to relinquish the Government's right to take title of such items. If the Contracting Officer agrees, prior to purchase, the Contractor shall have title to each such item having an acquisition cost less than $5,000. The Contractor shall furnish the Contracting Officer a list of all purchased property to which the Government has relinquished right to title within 10 days following the end of the calendar quarter during which the Contractor receives the property. The Contractor agrees that it will not allocate depreciation or amortization costs for such property to any existing or future Government contract and such property may be used by the Government or its subcontractors without charge in performance of any Government contract or subcontract thereunder. As a condition for the Government's relinquishing its rights to title under this clause, the Contractor, by signing this contract, agrees that—

No person in the United States shall, on the ground of race, color, or national origin, be excluded from participation in, be denied the benefits of, or be otherwise subjected to discrimination (42 U.S.C. 2000d) under this contemplated financial assistance (title to equipment, special tooling or special test equipment).

9. Section 252.245–7003 is added to read as follows:

252.245–7003 Government Property Control.

As prescribed in 245.102(c)(i), use the following clause:

Government Property Control (XXX 19XX)

(a) *Definitions.* The terms defined in the Right to Title—Equipment, Special Tooling, and Special Test Equipment clause of this contract have the same meaning in this clause.

(b) *General.* (1) This clause is applicable to Government furnished property and Government property stored by the Contractor at the Government's direction including property to which the Government has taken title under the Right to Title—Equipment, Special Tooling, and Special Test Equipment clause of this contract. It does not apply to property in which title is vested in the Government solely as a result of the financing provisions of this contract.

(2) The Contractor is responsible for the maintenance, protection, and preservation of Government property in its or its subcontractors' possession. The Contractor shall account for such property as required by this contract.

(3) If the Contractor does not have a property control system that is approved by the Government's property administrator, it shall establish a system that satisfies the requirements of this clause within 90 days following contract award (or such other mutually agreeable period). Notwithstanding any other provision of this contract regarding liability for loss, theft, or destruction of, or damage to, Government property in the Contractor's or its subcontractors' possession, the Contractor shall be liable for such loss, theft, destruction, or damage until its system is approved by the Government's property administrator. The Contractor shall maintain its system during the period Government property is in its or its subcontractors' possession.

(4) The Contractor should use its existing property control system or a modification thereof when the existing or modified system satisfies the requirements of this clause.

(c) *Control system requirements.* The property control system shall include written processes for—

(1) Assessing the system's efficiency and effectiveness, recommending corrective action or general improvements, and implementing appropriate changes;

(2) Obtaining approval of property actions from the responsible Government representative no later than the time specified in this contract (when such approval is required by this contract) and appropriately documenting such approval;

(3) Inspecting property acquired by the Contractor or furnished by the Government for performance of this contract upon receipt;

(4) Identifying Government property received by the Contractor that was intended for other persons or discrepancies between the type, quantity, or condition of Government furnished property shipped to and actually received by the Contractor and initiating corrective action;

(5) Promptly entering all Government property into the property control system;

(6) Ensuring that Government property is properly classified (see paragraph (f)(2)(viii) of this clause);

(7) Ensuring that Government property's used only as authorized by the Contracting Officer;

(8) Controlling the distribution and return of pilferable property;

(9) Scheduling and monitoring Government property maintenance to ensure timely performance and recording of all maintenance actions;

(10) Accurately recording by type and quantity Government furnished material consumed during contract performance;

(11) Performing, reporting, and recording all inventories required by this contract;

(12) Identifying and reporting lost, damaged, or destroyed Government property and generating corrective action recommendations;

(13) Maintaining special security for classified or sensitive property commensurate with the property's security classification, special handling requirements, or both;

(14) Accurately preparing and timely submitting the records and reports required by this contract;

(15) Ensuring the subcontractors have adequate procedures for the control and protection of Government property;

(16) Justifying the continued need for Government property to perform this contract;

(17) Moving and storing Government property in a manner commensurate with the property's handling and storage requirements; and

(18) Disposing of Government property in accordance with the requirements of this contract.

(d) *Access.* The Government shall have access, at all reasonable times, to the premises at which any Government property is located and to the Contractor's Government property records and supporting information.

(e) *Property control system submission, review, and approval.* (1) Except as provided in paragraph (e)(2) of this clause, offerors shall submit their written property control systems and processes with their offer if—

(i) The offeror does not have an existing property control system or its existing system has not been approved by a Government property administrator;

(ii) The offeror's property control system last was approved, or approval validated, more than 2 years prior to the date of its offer;

(iii) A Government property administrator has requested corrections to the offeror's system or procedures and such corrections have not been made; or

(iv) Approval of the system has been withdrawn.

(2) The submission requirements in paragraph (e)(1) of this clause do not apply to offerors that have a Government property system that has been approved or validated by the Government no more than 2 years prior to the time for submission offers. Such offerors are required only to submit to the Government's property administrator, within 90 days following contract award, changes required to conform the system with requirements in this contract. The submission date may be extended by the Government's property administrator if the property administrator determines that an extension is warranted.

(3) The Government's property administrator shall review the Contractor's system for conformance with contract requirements and approve or require corrections to the system and its implementing procedures. The Contractor shall accomplish the required corrections at no change in price or fee.

(4) The Government may review the Contractor's previously approved system or require the Contractor to review a subcontractor's system to assure compliance with contract requirements. The Government's property administrator may validate approval of, require corrections to, or with the Administrative Contracting Officer's concurrence, withdraw approval of the Contractor's system or require the Contractor to have a subcontractor's system corrected. The Contractor shall implement corrections required by the Government's property administrator by the date specified by the property administrator or such other date agreed upon at no change in price or fee. The Contractor's failure to implement corrections in a timely manner might result in the system's approval being withdrawn.

(5) The Contractor shall make available to the Government's property administrator all records and related information reasonably required to verify that the Contractor's or a subcontractor's property control system conforms to contract requirements. Any disagreement as to the amount or type of information required for such verification shall be referred to the Administrative Contracting Officer for resolution.

(f) *Property records and supporting information*—(1) *General.* (i) The Contractor shall establish or maintain a property record that is current and complete for each Government property item in its or its subcontractors' possession. Identical items may be consolidated in a single property record if the consolidated record provides the information required by this clause. The Contractor shall identify useable components permanently removed from Government property as Governmental property items, enter such items into its property control system, and establish and maintain appropriate property records. Property records created by a subcontractor that has an approved property system may be used in lieu of creating new records.

(ii) If the Contractor has an approved property control system, its documents evidencing receipt and issue shall be the property control records for Government material issued for immediate consumption.

(iii) When the Government is responsible for the replacement of a property item under this contract and has elected—

(A) To replace or have the Contractor replace the item, the Contractor shall annotate appropriately the property record for the item being replaced, close that record, and create a new property record for the replacement item; or

(B) Not to replace or have the Contractor replace the item, the Contractor shall close the property record for that item.

(iv) The Government shall provide the acquisition cost for Government furnished property within 30 days following delivery of the property to the Contractor. The Contractor shall notify the Government's property administrator promptly if the acquisition cost information is not received within the period.

(v) Property records are not required for work in process.

(2) *Standard information.* Each property control record shall contain the following information.

(i) The item's name, description, and national stock number (if the item has a national stock number). The national stock number for property controlled by documents evidencing that receipt and issue is not required until property disposal.

(ii) Contract number or equivalent code designation.

(iii) Quantity received, issued, and on hand.

(iv) The date of the most recent physical inventory or other posting reference.

(v) Acquisition cost.

(vi) Current location (for low value property, identify the initial location only).

(vii) The most recent transaction date.

(viii) The property's classification. (Use only one of the following for each property item: Land, Buildings, Other Real Property, Equipment, Special Test Equipment, Special Tooling, Unique Federal Property, or Material.)

(3) *Additional information*—(i) *Special test equipment records.* The Contractor shall provide the information required by paragraph (f)(2) of this clause for each general purpose test equipment item that is a removable or reusable component or Government owned special test equipment it removal and reuse is economically feasible.

(ii) *Equipment records.* Each record shall include the manufacturer's name, Commercial and Government Entity (CAGE) code or equivalent information, serial number, and model or part number.

(iii) *Real property records.* (A) Records are not required for portable buildings or facilities specifically acquired or constructed for tests that will result in the destruction of such buildings or facilities.

(B) Real property records must be itemized, indexed, and contain a description of the property, its location, original acquisition cost, a description of property alterations made or construction work performed by the Contractor including an identification of the construction sites supporting such alterations or construction, and separately identify the cost of such alterations or construction. Supporting documentation shall include maps, drawings, plans, specifications, and, if necessary, supplementary data needed to completely describe and value the property.

(C) Costs incurred by the Government or the Contractor, to acquire, construct, alter, or improve Government owned or leased real property, including additions, expansions, extensions, conversions, shall be added to the property's acquisition cost if they increase the value, life, utility, capability, or serviceability of the property.

(D) The real property records shall be modified and annotated with a statement of the pertinent facts when property is sold, transferred, donated, destroyed, abandoned by the Government in place, or condemned.

(iv) *Records of maintenance actions.* The property records for items requiring maintenance shall contain the maintenance schedule, the dates maintenance actions were performed, and identify and deficiencies discovered.

(v) *Scrap records.* (A) The scrap records shall provide the—

(1) Contract number or equivalent code designation from which the scrap was derived;

(2) Scrap classification by material content; and

(3) Disposition and disposition dates.

(B) When Contractor and Government owned property of the same stock or classification are used to produce an item or any component thereof and property scrapped during such production cannot be identified as Contractor or Government owned property, the Government property scrap records shall reflect a proportional, equitable share of such scrap.

(vi) *Property returned under warranty.* The Contractor shall establish a separate property record for each item returned for correction under a warranty and maintain the records on a contract-by-contract basis. The records shall identify the date received, the contract number under which the item was returned, the corrective action performed, and the date the item is returned to the Government. Once a property record has been established, identical items received for corrective action shall be added to the established record and the information required by this paragraph maintained for each item.

(vii) *Sensitive property.* Property records shall legibly and conspicuously identify sensitive property.

(g) *Reports*—(1) *Government property.* The Contractor shall report all Government property accountable under this contract that is in its or its subcontractors' possession as of September 30 of each calendar year or upon completion of all property disposal actions under this contract, whichever is sooner. The report shall be prepared using Standard Form 1422, U.S. Government Property in the Custody of Contractors (or an agency equivalent furnished by the Contracting Officer), and submitted to the Government's property administrator no later than October 31 of each calendar year.

(2) *Misdirected Government property.* The Contractor shall submit a written report to the Government's property administrator immediately following receipt of Government property intended for another person or Government property not required for performance of a Government contract and request disposition instructions. To the extent practical, the report shall identify the shipment's content, the intended recipient, the carrier that made delivery, the Government activity from which the shipment originated, and the shipment's current location.

(3) *Late Government furnished property.* The Contractor shall report to the Contracting Officer, with a concurrent copy to the Government's property administrator, a failure to receive Government furnished property at the time stated in the contract or, when a time is not stated, in sufficient time to enable the Contractor to meet the contract's delivery or performance dates. Each report shall forward the Contractor's estimate of the extent to which such failure has affected or might affect contract performance.

(h) *Physical inventories.*—(1) *Periodic.* Except for low value property and work in process, the Contractor shall periodically physically inventory all Government property in its possession. The Contractor, with the approval of the property administrator, shall establish the method, frequency, and procedures for such inventories to ensure that the existence and location of such property are accurately established and the records and reports required by this clause are complete and accurate. For purposes of this clause, electronic, optical, electro-magnetic, or similar inventory systems approved by the Government's property administrator satisfy the requirement for physical inventories.

(2) *Contract termination or completion inventories.* The Contractor shall inventory all property furnished by the Government and all property to which the Government has taken title under this contract immediately following a notice of

termination or partial termination of this contract or upon completion of deliveries or performance under the contract except property that is authorized for use on a follow-on or other Government contract. Such property does not have to be inventoried if the Contractor has notified the property administrator that record balances have been transferred to the receiving contract.

(3) *Restriction.* The Contractor personnel who perform physical inventories shall not be the same individuals who maintain the property records required by this contract or have custody of the property unless authorized to do so by the property administrator.

(i) *Markings.* Promptly following receipt of Government furnished property, the Contractor shall determine whether the property bears a Government ownership marking, legibly and conspicuously mark unmarked property with the phrase ''U.S. Government Property'' (or a similar phrase that conveys Government ownership), and replace any control numbers affixed by others with the Contractor's control number.

(j) *Overseas contracts.* In a contract performed outside the United States, its territories, or possessions, the words ''Government'' and ''Government furnished,'' as used in this clause, mean ''United States Government'' and ''United States Government furnished,'' respectively.

(End of clause)

ALTERNATE I (XXX 19XX) As prescribed in 245.102(c)(ii), substitute the following paragraphs (f) and (g) for paragraphs (f) and (g) of the basic clause:

(f) *Property records.* The Contractor shall establish a separate property record for each Government property item returned for correction under a warranty and maintain the records on a contract-by-contract basis. The records shall identify the item's name, description, property classification, and national stock number (if the item has a national stock number), the date received, the contract number under which the item was returned, the corrective action performed, and the date the item is returned to the Government. Once a property record has been established, identical items received for corrective action shall be added to the established record and the information required by this paragraph maintained for each item.

(g) *Reports.*—(1) *Misdirected Government property.* The Contractor shall submit a written report to the Government's property administrator immediately following receipt of Government property intended for another person or Government property not required for performance of a Government contract and request disposition instructions. To the extent practical, the report shall identify the shipment's content, the intended recipient, the carrier that made delivery, the Government activity from which the shipment originated, and the shipment's current location.

(2) *Late Government furnished property.* The Contractor shall report to the Contracting Officer, with a concurrent copy to the Government's property administrator, a failure to receive Government furnished property at the time stated in the contract or, when a time is not stated, in sufficient time to enable the Contractor to meet the contract's delivery or performance dates. Each report shall forward the Contractor's estimate of the extent to which such failure has affected or might affect contract performance.

[FR Doc. 97–27438 Filed 10–16–97; 8:45 am]

BILLING CODE 5000–04–M

DEPARTMENT OF DEFENSE

48 CFR Part 252

[DFARS Case 97–D029]

Defense Federal Acquisition Regulation Supplement; Reporting of Contract Performance Outside the United States

AGENCY: Department of Defense (DoD).

ACTION: Proposed rule with request for comments.

SUMMARY: The Director of Defense Procurement is proposing to amend the Defense Federal Acquisition Regulation Supplement (DFARS) to raise the threshold for reporting contract performance outside the United States from $25,000 to the simplified acquisition threshold, under contracts exceeding $500,000.

DATES: Comment date: Comments on the proposed rule should be submitted in writing to the address shown below on or before December 16, 1997, to be considered in the formulation of the final rule.

ADDRESSES: Interested parties should submit written comments to: Defense Acquisition Regulations Council, Attn: Ms. Amy Williams, PDUSD (A&T) DP (DAR), IMD 3D139, 3062 Defense Pentagon, Washington, DC 20301–3062. Telefax number (703) 602–0350.

E-mail comments submitted over the Internet should be addressed to: dfars@acq.osd.mil

Please cite DFARS Case 97–D029 in all correspondence related to this issue. E-mail comments should cite DFARS Case 97–D029 in the subject line.

FOR FURTHER INFORMATION CONTACT: Ms. Amy Williams, (703) 602–0131.

SUPPLEMENTARY INFORMATION:

A. Background

The clause at DFARS 252.225–7026, Reporting of Contract Performance Outside the United States, presently requires a contractor to submit a report to the Deputy Director of Defense Procurement (Foreign Contracting) under a contract exceeding $500,000, when any part that exceeds $25,000 will be performed outside the United States, unless a foreign place of performance is the principal place of performance and was indicated as such in the offer for the contract. This rule proposes to increase the $25,000 threshold to the simplified acquisition threshold ($100,000). In addition, the rule proposes to increase the threshold for incorporation of the clause in first-tier subcontracts from $100,000 to $500,000. These amendments are expected to reduce information collection requirements by approximately 40 percent.

B. Regulatory Flexibility Act

The proposed rule is not expected to have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.* Annually, approximately 55 contractors submit a total of approximately 1400 reports of contract performance outside the United States. Reporting varies from 1 to 50 reports per contractor. Most of the contractors that submit the reports are not small businesses, and the report is not excessively time-consuming. An initial regulatory flexibility analysis has therefore not been performed. Comments are invited from small businesses and other interested parties. Comments from small entities concerning the affected DFARS subpart also will be considered in accordance with 5 U.S.C. 610. Such comments should be submitted separately and should cite DFARS Case 97–D029 in correspondence.

C. Paperwork Reduction Act

The rule will result in a reduction of paperwork burden on contractors. The clause at DFARS 252.225–7026 presently has an approved annual information collection requirement of 900 hours under Office of Management and Budget Clearance Number 0704–0229. Based on a review of 1995 and 1996 data, it is estimated that the amendments in this rule will reduce annual information collection requirements by approximately 360 hours.

List of Subjects in 48 CFR Part 252

Government procurement.

Michele P. Peterson,

Executive Editor, Defense Acquisition Regulations Council.

Therefore, 48 CFR part 252 is proposed to be amended as follows:

1. The authority citation for 48 CFR Part 252 continues to read as follows:

Authority: 41 U.S.C. 421 and 48 CFR Chapter 1.

PART 252—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

2. Section 252.225–7026 is amended by revising the clause date and the introductory text of paragraph (a)(3); by redesignating paragraphs (d)(i), (d)(ii), and (d)(iii) as paragraphs (d)(1), (d)(2), and (d)(3), respectively; and by revising paragraph (c)(1). The revised text reads as follows:

252.225–7026 Reporting of Contract Performance Outside the United States.

* * * * *

REPORTING OF CONTRACT PERFORMANCE OUTSIDE THE UNITED STATES (XXX 19XX)

(a) * * *

(3) Contracts exceeding $500,000, when any part that exceeds the simplified acquisition threshold in Part 2 of the Federal Acquisition Regulation will be performed outside the United States, unless a foreign place of performance is—

* * * * *

(c) * * *

(1) The Contractor shall include a clause substantially the same as this one in all first-tier subcontracts exceeding $500,000, except subcontracts for commercial items, construction, ores, natural gases, utilities, petroleum products and crudes, timber (logs), or subsistence.

* * * * *

[FR Doc. 97–27437 Filed 10–16–97; 8:45 am]
BILLING CODE 5000–04–M

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 227

Endangered and Threatened Wildlife and Plants; 90-Day Finding for a Petition To List the Atlantic Sturgeon (Acipenser oxyrhinchus oxyrhinchus) in the United States as Endangered or Threatened

AGENCY: Fish and Wildlife Service, Interior; National Marine Fisheries Service, National Oceanic and Atmospheric Administration, Commerce.

ACTION: Notice of 90-day petition finding and request for information.

SUMMARY: The U.S. Fish and Wildlife Service and the National Marine Fisheries Service (collectively the ''Services'') announce a 90-day finding for a petition to add the Atlantic sturgeon (*Acipenser oxyrhinchus oxyrhinchus*), where it continues to exist in the United States, to the List of Threatened and Endangered Wildlife and to designate critical habitat. The Services find that the petition presents substantial information indicating that the petitioned action to list Atlantic sturgeon may be warranted. The Services are now initiating a status review to determine whether listing of the Atlantic sturgeon in its North American range, including Atlantic Canada, is warranted, and to prepare a 12-month finding. To assure that the review is comprehensive, the Services are soliciting information and data on this species.

DATES: The finding announced in this document was made on October 2, 1997. Comments and materials related to this petition finding must be submitted to National Marine Fisheries Service, Northeast Region, Habitat and Protected Resources Division, at the **ADDRESS** below, by December 16, 1997, to be considered in the 12-month finding.

ADDRESSES: Information, comments or questions concerning the Atlantic sturgeon petition should be submitted to Christopher Mantzaris, Chief, Habitat and Protected Resources Division, National Marine Fisheries Service, One Blackburn Drive, Gloucester, Massachusetts 01930. The petition, finding, supporting data, and comments are available for public inspection by appointment during normal business hours at the above address.

FOR FURTHER INFORMATION CONTACT: Mary Colligan (508–281–9116) or Ray Santos (508–281–9103) at the above address, or Anne Hecht of the U.S. Fish and Wildlife Service (508-443–4325).

SUPPLEMENTARY INFORMATION:

Background

Section 4(b)(3)(A) of the Endangered Species Act of 1973, as amended (ESA) (16 U.S.C. 1531–1544) requires that the Services make a finding on whether a petition to list, delist or reclassify a species presents substantial scientific or commercial information to indicate that the petitioned action may be warranted. To the maximum extent practicable, this finding is to be made within 90 days of the receipt of the petition, and the finding is to be published promptly in the **Federal Register**. If the finding is positive, the Services are required to commence a status review of Atlantic sturgeon and to disclose their findings within 12 months of receipt of the petition (12-month finding).

On June 2, 1997, a petition dated May 29, 1997, was received by the Services from the Biodiversity Legal Foundation. The petitioner requested the Services to list Atlantic sturgeon, in the United States where it continues to exist, as threatened or endangered and to designate critical habitat within a reasonable period of time following the listing. The petitioner submitted biological, distributional, and historical information on Atlantic sturgeon populations and identified potential threats including commercial fishing (directed and incidental), river damming, habitat loss, and water quality. Also, the petitioner cited scientific references in support of the petition.

There are two subspecies of Atlantic sturgeon. The first subspecies, *Acipenser oxyrhinchus desotoi*, known as Gulf sturgeon, occurs from the Mississippi River to Tampa Bay, Florida. This subspecies was listed in 1991 as threatened under the ESA. The petition and this finding address the second subspecies, *Acipenser oxyrhinchus oxyrhinchus*, known as the Atlantic sturgeon, which is distributed in the western North Atlantic from Hamilton Inlet, Labrador, south to the St. Lucie River, Florida.

Atlantic sturgeon are anadromous fish that may live up to 60 years, reach lengths of up to 4 meters (m) (14 feet (ft)), and weigh over 363 kilograms (kg) (800 pounds (lb)). They are distinguished by armor-like plates and a long protruding snout. Ventrally located on the snout is a protruding mouth with four barbels crossing in front. Sturgeon are omnivorous benthic feeders eating opportunistically and filtering quantities of mud along with their food. Adult sturgeon diets include mollusks, gastropods, amphipods, isopods, and fish. Juvenile sturgeon feed on aquatic insects and other invertebrates.

Depending on geographic location and sex, sturgeon reach sexual maturity at different ages. Males tend to reach maturity faster than females and the average age of maturity for both males and females increases with increasing latitude along the Atlantic coast. Age at sexual maturity for males ranges from 5 to 24 years, and for females, from 7 to 30 years (ASMFC 1990). Sexually mature sturgeon begin their spawning run as early as March (in the southern Atlantic coast) and as late as July (in the higher latitudes). Spawning occurs in flowing fresh or estuarine waters with a hard bottom, where the extremely adhesive eggs stick together in clusters. After hatching, juveniles may remain in

fresh/estuarine waters for several years. Juveniles then head seaward to grow to maturity and join the adult migration run which can range many miles away from their home rivers.

Historical records from the early 1800s document large numbers of sturgeon in many river systems along the Atlantic coast. It does not appear that the historical range has been reduced significantly; however, remnant populations in some river systems, if not extirpated, are quite small. Systems presently known to support reproducing populations are the Hudson River in New York, the Ashepoo-Combahee-Edisto River system in South Carolina, and the Altamaha and Savannah rivers in Georgia (ASMFC 1997). In the Hudson River, numbers of juvenile sturgeon were estimated at less than 5,000 during 1994, an 80 percent decline from the 25,000 juveniles believed to have been in the Hudson during the 1970s (New York State Department of Environmental Conservation 1996). Recent documentation of gravid females and/or young of the year exists for the Delaware River (DE), James River (VA), Roanoke/Chowan and Cape Fear rivers (NC), and Santee/Cooper rivers (SC) (W. Laney, USFWS, pers. comm., 1997). Additional research is needed to determine the extent of reproduction, if any, in these rivers.

Both commercial fishing and incidental take may have a substantial effect on Atlantic sturgeon. Commercial fishing is frequently cited as a major reason for the species' decline. Historical commercial landings provide the only long-term estimates of stock abundance; unfortunately, Atlantic and shortnose sturgeon were probably not differentiated in those records. Annual commercial harvest levels reached approximately 3 million kg (7 million lb) at the end of the nineteenth century. Since that time, a severe decline took place with annual United States commercial landings not exceeding 136,000 kg (300,000 lb) (ASMFC 1990). In addition to directed commercial fishing for sturgeon, incidental catches of juvenile and adult sturgeon in State and Federal waters are frequently reported as having a substantial impact on stocks. Coast-wide, the 1987 incidental catch exceeded the directed catch (ASMFC 1990). Current information indicates that Atlantic sturgeon are taken incidentally in every commercial type of fishing gear.

Prior to 1990, commercial landings averaged between 91,000 and 136,000 kg (200,000 and 300,000 lb) per year. In 1990, the Atlantic States Marine Fisheries Commission (ASMFC), developed an Interstate Fishery Management Plan for Atlantic sturgeon regulating harvest and initiated a coordinated stock assessment from Maine to Florida. The goal of the plan is to provide framework for the restoration of Atlantic sturgeon to fishable abundance throughout its range. The plan recommended that the states control harvests by adopting either—(1) A minimum length of 2.4 m (7 ft); (2) a moratorium on all harvest; or (3) alternative measures determined to be conservationally equivalent. Coast-wide landings fell to less than 45,000 kg (100,000 lb) by 1994; but in 1996, the ASMFC determined that the current harvest levels were still too large for stock recovery. Subsequently, all but two states have banned harvest and those (Delaware and Connecticut) have reported no landings. Currently, the ASMFC is considering an amendment to the plan to institute a coast-wide moratorium. Due to the current low levels of abundance, long life cycle, and sporadic spawning, a moratorium would likely have to last decades to allow stock recovery.

Other threats to Atlantic sturgeon and their habitat include habitat loss and degradation, and disease. Dams, mostly constructed during the 1800s, destroyed riverine habitat and impeded access to upstream areas, and may have played a role in the historic decline of this species. Biologists also suspect that siltation and water pollution may be factors in recent sturgeon reproduction declines, but the extent is unknown (R. St. Pierre, USFWS, pers. comm., 1997). Transportation of white sturgeon to the Atlantic coast for the pet trade may cause genetic and health impacts (disease) to Atlantic sturgeon if released into the wild (Laney, pers. comm., 1997).

The Services have determined that the petitioners have adequately presented information about the status, distribution, and abundance of Atlantic sturgeon, in addition to having identified potential threats to the species in the United States. After review of the petition and information available within the agencies' records, the Services find that substantial information has been presented to indicate that the petitioned action to list the Atlantic sturgeon may be warranted. A status review will now be conducted on the Atlantic sturgeon in North America, including Atlantic Canada. While the petition was limited to U.S. populations of sturgeon, the Services have decided to expand their review to encompass the entire North American range. Existing information indicates Atlantic sturgeon undertake long migrations and therefore a broader scope is required to understand stock structure throughout its range.

Within one year from the date the petition was received, a finding will be made as to whether listing the Atlantic sturgeon is warranted, as required by section 4(b)(3)(B) of the ESA. The petitioner also requested that critical habitat be designated. If the 12-month finding determines that the petitioned action to list the Atlantic sturgeon as threatened or endangered is warranted, then the designation of critical habitat would be addressed at that time.

Listing Factors and Basis for Determination

Under section 4(a)(1) of the ESA, a species can be determined to be threatened or endangered for any one of the following reasons—(1) Present or threatened destruction, modification, or curtailment of habitat or range; (2) overutilization for commercial, recreational, scientific, or educational purposes; (3) disease or predation; (4) inadequacy of existing regulatory mechanisms; or (5) other natural or manmade factors affecting its continued existence. Listing determinations are made solely on the best scientific and commercial data available.

Information Solicited

To ensure that the status review is complete and based on the best available scientific and commercial data, the Services are soliciting information concerning the following—(1) Current and historical abundance and distribution of Atlantic sturgeon; (2) existence and viability of reproducing populations; (3) threats to the species and its habitat (fresh, estuarine, and marine); (4) ongoing efforts to protect Atlantic sturgeon and their habitat; and (5) whether or not any population is threatened or endangered based upon the above listing criteria. The Services request that data, information, and comments be accompanied by—(1) Supporting documentation such as maps, bibliographic reference, or reprints of pertinent publications; and (2) the person's name, address, and any association, institution, or business that the person represents. Such information may be submitted to the above address.

References Cited

ASMFC Fisheries Focus. 1997. Species profile: Atlantic Sturgeon. Atlantic States Marine Fisheries Commission, Vol. 6, Iss. 3: pp. 4–7.

ASMFC Draft Public Information Document. 1996. Amendment 1 to the Fishery Management Plan for Atlantic Sturgeon. Pp. 1–9.

ASMFC Fisheries Management Report No. 17. 1990. Fishery Management Plan for Atlantic Sturgeon. Atlantic States Marine Fisheries Commission, Nov. 1990. 73 pp.

New York State Department of Environmental Conservation. 1996. DEC Announces Emergency Moratorium on Atlantic Sturgeon. News Release dated March 22, 1996.

List of Subjects

50 CFR Part 17

Endangered and threatened species, Exports, Imports, Reporting and recordkeeping requirements, Transportation.

50 CFR Part 227

Endangered and threatened species, Exports, Imports, Marine mammals, Transportation.

Authority: The authority for this action is the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Dated: September 29, 1997.

Jamie Rappaport Clark,

Director, U.S. Fish and Wildlife Service.

Dated: October 2, 1997.

David L. Evans,

Deputy Assistant Administrator for Fisheries, National Marine Fisheries Service.

[FR Doc. 97–27547 Filed 10–16–97; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

RIN 1018–AE36

Endangered and Threatened Wildlife and Plants; Proposed Rule to List Three Aquatic Snails as Endangered, and Three Aquatic Snails as Threatened in the Mobile River Basin of Alabama

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule and notice of petition findings.

SUMMARY: The Fish and Wildlife Service (Service) proposes to list the cylindrical lioplax (*Lioplax cyclostomaformis*), flat pebblesnail (*Lepyrium showalteri*), and plicate rocksnail (*Leptoxis plicata*) as endangered; and the painted rocksnail (*Leptoxis taeniata*), round rocksnail (*Leptoxis ampla*), and lacy elimia (*Elimia crenatella*) as threatened species under the authority of the Endangered Species Act of 1973, as amended (Act). These aquatic snails are found in localized portions of the Black Warrior, Cahaba, Alabama, and Coosa rivers or their tributaries in Alabama. Impoundment and water quality degradation have eliminated the six snails from 90 percent or more of their historic habitat. Surviving populations are currently threatened by pollutants such as sediments and nutrients that wash into streams from the land surface. This proposed rule, if made final, would extend the Act's protection to these six snail species.

DATES: Comments from all interested parties must be received by December 16, 1997. Public hearing requests must be received by December 1, 1997.

ADDRESSES: Comments and materials concerning this proposal should be sent to the Field Supervisor, U.S. Fish and Wildlife Service, 6578 Dogwood View Parkway, Jackson, Mississippi 39213. Comments and materials received will be available for public inspection, by appointment, during normal business hours at the above address.

FOR FURTHER INFORMATION CONTACT: Mr. Paul Hartfield at the above address, or telephone 601/965–4900, Ext. 25.

SUPPLEMENTARY INFORMATION:

Background

The Mobile River Basin (Basin) historically supported the greatest diversity of freshwater snail species in the world (Bogan *et al.* 1995), including six genera and over 100 species that were endemic to the Basin. During the past few decades, publications in the scientific literature have primarily dealt with the apparent decimation of this fauna following the construction of dams within the Basin and the inundation of extensive shoal habitats by impounded waters (Goodrich 1944, Athearn 1970, Heard 1970, Stein 1976, Palmer 1986, Garner 1990).

In 1990, the Service initiated a status review of the endemic freshwater snails of the Basin. An extensive literature survey identified sources of information on taxonomy, distribution, ecology, and status of the fauna and was used to assemble a checklist of the Basin's snails and their distributions (Bogan 1992). Field surveys and collections were made for snails and other freshwater mollusks throughout the Basin (Bogan and Pierson, 1993a,b; McGregor *et al.* 1996; Service Field Records, Jackson, Mississippi 1989–1996; Bogan *in litt.* 1995; M. Pierson Field Records, Calera, Alabama, *in litt.* 1993–1994; J. Garner, Alabama Department of Conservation, pers. comm. 1996; J. Johnson, Auburn University, *in litt.* 1996).

Bogan *et al.* (1995) summarized the results of their efforts noting the apparent extinction of numerous snail species in the Coosa and Cahaba River drainages, and the imperiled state of many other aquatic snails in the Basin.

The taxonomy used in this proposal follows Burch (1989), which relies almost exclusively on shell morphology. Many of the Basin's freshwater snail species, particularly in the family Pleuroceridae, are known to exhibit marked clinal variation (gradual change in characters of a species that manifests itself along a geographic gradient) in shell form, some of which has been described as environmentally induced (e.g., Goodrich 1934, 1937). Four of the six species considered in this proposal belong to the family Pleuroceridae and their relationships to each other, as well as to other Pleuroceridae, are poorly understood. In order to better document taxonomic relationships among these snails, a genetic study was conducted during the status review of a select group of the Basin's Pleuroceridae (Lydeard *et al.* 1997). The four snails within this family considered herein (lacy elimia, round rocksnail, plicate rocksnail, and painted rocksnail) were included in the genetic study. This study supported their current taxonomic status (Lydeard *et al.* 1997).

The cylindrical lioplax (*Lioplax cyclostomaformis* (Lea 1841)) is a gill-breathing snail in the family Viviparidae. The shell is elongate, reaching about 28 millimeters (mm) (1.1 inches (in)) in length. Shell color is light to dark olivaceous-green externally, and bluish inside of the aperture (shell opening). The cylindrical lioplax is distinguished from other viviparid snails in the Basin by the number of whorls, and differences in size, sculpture, microsculpture, and spire angle. No other species of lioplax snails are known to occur in the Mobile Basin (see Clench and Turner 1955 for a more detailed description).

Habitat for the cylindrical lioplax is unusual for the genus, as well as for other genera of viviparid snails. It lives in mud under large rocks in rapid currents over stream and river shoals.

Other lioplax species are usually found in exposed situations or in mud or muddy sand along the margins of rivers. Little is known of the biology or life history of the cylindrical lioplax. It is believed to brood its young and filter-feed, as do other members of the Viviparidae. Life spans have been reported from 3 to 11 years in various species of Viviparidae (Heller 1990).

Collection records for the cylindrical lioplax exist from the Alabama River (Dallas County, Alabama), Black Warrior River (Jefferson County, Alabama) and tributaries (Prairie Creek, Marengo County, Alabama; Valley Creek, Jefferson County, Alabama), Coosa River

(Shelby, Elmore counties, Alabama) and tributaries (Oothcalooga Creek, Bartow County, Georgia; Coahulla Creek, Whitfield County, Georgia; Armuchee Creek, Floyd County, Georgia; Little Wills Creek, Etowah County, Alabama; Choccolocco Creek, Talladega County, Alabama; Yellowleaf Creek, Shelby County, Alabama), and the Cahaba River (Bibb, Shelby counties, Alabama) and its tributary, Little Cahaba River (Jefferson County, Alabama) (Clench and Turner 1955). A single collection of this species has also been reported from the Tensas River, Madison Parish, Louisiana (Clench 1962), however, there are no previous or subsequent records outside of the Alabama-Coosa system, and searches of the Tensas River in Louisiana by Service biologists (1995) and others (Vidrine 1996) have found no evidence of the species or its typical habitat.

The cylindrical lioplax is currently known only from approximately 24 kilometers (km) (15 miles (mi)) of the Cahaba River above the Fall Line in Shelby and Bibb counties, Alabama (Bogan and Pierson 1993b). Survey efforts by Davis (1974) failed to locate this snail in the Coosa or Alabama rivers, and more recent survey efforts have also failed to relocate the species at historic localities in the Alabama, Black Warrior, Little Cahaba, and Coosa rivers and their tributaries (Bogan and Pierson 1993a, 1993b; M. Pierson *in litt.* 1993, 1994; Service Field Records 1991, 1992, 1993).

The flat pebblesnail (*Lepyrium showalteri* (Lea 1861)) is a small snail in the family Hydrobiidae; however, the species has a large and distinct shell, relative to other hydrobiid species. This snail's shell is also distinguished by its depressed spire and expanded, flattened body whorl. The shells are ovate in outline, flattened, and grow to 3.5 to 4.4 mm (0.1–0.2 in) high and 4 to 5 mm (0.2 in) wide. The umbilical area is imperforate (no opening), and there are 2 to 3 whorls which rapidly expand. The anatomy of this species has been described in detail by Thompson (1984). The flat pebblesnail is found attached to clean, smooth stones in rapid currents of river shoals. Eggs are laid singly in capsules on hard surfaces (Thompson 1984). Little else is known of the natural history of this species.

The flat pebblesnail was historically known from the mainstem Coosa River in Shelby and Talladega counties, the Cahaba River in Bibb and Dallas counties, and Little Cahaba River in Bibb County, Alabama (Thompson 1984). The flat pebblesnail has not been found in the Coosa River portion of its range since the construction of Lay and Logan Martin Dams, and recent survey efforts have failed to locate any surviving populations outside of the Cahaba River drainage (Bogan and Pierson, 1993a,b; McGregor *et al.* 1996; Service Field Records, Jackson, Mississippi 1989–1996; Bogan *in litt.* 1995; M. Pierson Field Records, Calera, Alabama, *in litt.* 1993–1994; J. Garner pers. comm. 1996; J. Johnson *in litt.* 1996). The flat pebblesnail is currently known from one site on the Little Cahaba River, Bibb County, and from a single shoal series on the Cahaba River above the Fall Line, Shelby County, Alabama (Bogan and Pierson 1993b).

The lacy elimia (*Elimia crenatella* (Lea 1860)) is a small species in the family Pleuroceridae. Growing to about 1.1 centimeters (cm) (0.4 in.) in length, the shell is conic in shape, strongly striate, and often folded in the upper whorls. Shell color is dark brown to black, often purple in the aperture, and without banding. The aperture is small and ovate. The lacy elimia is easily distinguished from other elimia species by a combination of characters (i.e., size, ornamentation, color).

In a recent genetic sequence study of the 16S rRNA gene, the lacy elimia was found to be very similar to the compact elimia (*Elimia showalteri*) (Lydeard *et al.* 1997). Despite their apparent close genetic relationship, the authors made no suggestion that the two species represented a single species. Upon review of Lydeard *et al.* (1997), Dillon (College of Charleston, Charleston, South Carolina, *in litt.* 1997) suggested that additional genetic studies were needed to demonstrate the genetic uniqueness of the lacy elimia. However, the Lydeard *et al.* (1997) genetic study addressed only one small genetic character of the genome of these species, and other characters strongly support the taxonomic status of the lacy elimia. The two species are allopatric (the compact elimia occurs in the Cahaba River, whereas the lacy elimia was found in the Coosa River and tributaries), and are strikingly different in size, appearance, and behavior. The compact elimia has a large, robust, smooth shell boldly colored brown and/or green, whereas the lacy elimia has a small, delicate, darkly colored, and ornamented shell. The lacy elimia is one of the few elimia snails in the Basin that does not exhibit clinal variation (Goodrich 1936). In addition, compact elimia are found grazing individually throughout shoal habitats, whereas the lacy elimia is usually found in tight clusters or colonies on larger rocks within a shoal (P. Hartfield, Jackson, MS, pers. obsv.). Allopatry, morphology, and behavior are strong characters supporting species specific status of the lacy elimia.

Elimia snails are gill breathing snails that typically inhabit highly oxygenated waters on rock shoals and gravel bars. Most species graze on periphyton growing on benthic substrates. Individual snails are either male or female. Eggs are laid in early spring and hatch in about 2 weeks. Snails apparently become sexually mature in their first year, but, in some species, females may not lay until their second year. Some elimia may live as long as 5 years (Dillon 1988).

The lacy elimia was historically abundant in the Coosa River main stem from St. Clair to Chilton County, Alabama, and was also known in several Coosa River tributaries—Big Will's Creek, DeKalb County; Kelley's Creek, St. Clair County; and Choccolocco and Tallaseehatchee creeks, Talladega County, Alabama (Goodrich 1936). The lacy elimia has not been recently located at any historic collection site. However, as a result of the recent survey efforts previously unreported populations were discovered in three Coosa River tributaries—Cheaha, Emauhee, and Weewoka creeks, Talladega County, Alabama (Bogan and Pierson 1993a). The species is locally abundant in the lower reaches of Cheaha Creek. This stream originates within the Talladega National Forest; however, no specimens of the lacy elimia have been collected on Forest Service lands. The species has also been found at single sites in Emauhee and Weewoka creeks, where specimens are rare, and difficult to locate.

The painted rocksnail (*Leptoxis taeniata* (Conrad 1834)) is a small to medium snail about 19 mm (0.8 in.) in length, and subglobose to oval in shape. The aperture is broadly ovate, and rounded anteriorly. Coloration varies from yellowish to olive-brown, and usually with four dark bands. Some shells may not have bands and some have the bands broken into squares or oblongs (see Goodrich 1922 for a detailed description). All of the rocksnails that historically inhabited the Basin had broadly rounded apertures, oval shaped shells, and variable coloration. Although the various species were distinguished by relative sizes, coloration patterns, and ornamentation, identification could be confusing. However, the painted rocksnail is the only known survivor of the 15 rocksnail species that were historically known from the Coosa River drainage.

Rocksnails are gill breathing snails found attached to cobble, gravel, or other hard substrates in the strong currents of riffles and shoals. Adult

rocksnails move very little, and females probably glue their eggs to stones in the same habitat (Goodrich 1922). Heller (1990) reported a short life span (less than 2 years) in a Tennessee River rocksnail. Longevity in the painted and the Basin's other rocksnails is unknown.

The painted rocksnail had the largest range of any rocksnail in the Mobile River Basin (Goodrich 1922). It was historically known from the Coosa River and tributaries from the northeastern corner of St. Clair County, Alabama, downstream into the mainstem of the Alabama River to Claiborne, Monroe County, Alabama, and the Cahaba River below the Fall Line in Perry and Dallas counties, Alabama (Goodrich 1922, Burch 1989). Surveys by Service biologists and others (Bogan and Pierson 1993a, 1993b; M. Pierson, *in litt.* 1993) in the Cahaba River, unimpounded portions of the Alabama River, and a number of free-flowing Coosa River tributaries have located only three localized Coosa River drainage populations.

The painted rocksnail is currently known from the lower reaches of three Coosa River tributaries—Choccolocco Creek, Talladega County; Buxahatchee Creek, Shelby County (Bogan and Pierson 1993a); and Ohatchee Creek, Calhoun County, Alabama (Pierson *in litt.* 1993).

The round rocksnail (*Leptoxis ampla* (Anthony 1855)) grows to about 20 mm (0.8 in) in length. The shell is subglobose, with an ovately rounded aperture. The body whorl is shouldered at the suture, and may be ornamented with folds or plicae. Color may be yellow, dark brown, or olive green, usually with four entire or broken bands (Goodrich 1922). Round rocksnails inhabit riffles and shoals over gravel, cobble, or other rocky substrates.

Lydeard *et al.* (1997) found slight differences in DNA sequencing between the painted rocksnail and the round rocksnail, and considered them to be sister species. Following analysis by allozyme electrophoresis on these same species, Dillon (*in litt.* 1997) speculated that the two species represented isolated populations belonging to a single species. The two species are geographically separated, with the painted rocksnail inhabiting Coosa River tributaries, while the round rocksnail is the only surviving rocksnail species in the Cahaba River drainage. Both species are currently recognized by the malacological community (e.g., Burch 1989; Turgeon *et al.* 1988, revision in review), and are treated as distinct in this proposed rule.

The round rocksnail was historically found in the Cahaba River, and its tributary, Little Cahaba River, Bibb County, Alabama; and the Coosa River, Elmore County, and tributaries—Canoe Creek and Kelly's Creek, St. Clair County; Ohatchee Creek, Calhoun County; Yellowleaf Creek, Shelby County; and Waxahatchee Creek, Shelby/Chilton counties, Alabama (Goodrich 1922).

The round rocksnail is currently known from a shoal series in the Cahaba River, Bibb and Shelby counties, Alabama, and from the lower reach of the Little Cahaba River, and the lower reaches of Shade and Six-mile creeks in Bibb County, Alabama (Bogan and Pierson 1993b).

The plicate rocksnail (*Leptoxis plicata* (Conrad, 1834)) grows to about 20 mm (0.8 in) in length. Shells are subglobose with broadly rounded apertures. The body whorl may be ornamented with strong folds or plicae. Shell color is usually brown, occasionally green, and often with four equidistant color bands. The columella (central column or axis) is smooth, rounded, and typically pigmented in the upper half. The aperture is usually bluish-white, occasionally pink or white. The operculum (plate that closes the shell when the snail is retracted) is dark red, and moderately thick (Goodrich 1922). Although morphologically similar to the Basin's other three surviving rocksnail species, the plicate rocksnail is genetically distinct (Lydeard *et al.* 1997, Dillon *in litt.* 1997).

The plicate rocksnail historically occurred in the Black Warrior River and its tributary, the Little Warrior River, and the Tombigbee River (Goodrich 1922). Status survey efforts found populations of plicate rocksnails only in an approximately 88km (55 mi) reach of the Locust Fork of the Black Warrior River, Jefferson and Blount counties, Alabama (Service Field Records, Jackson, Mississippi 1991, 1992; Malcolm Pierson, Calera, Alabama, Field Notes 1993). Surveys during 1996 (Garner in progress) indicate that the snail has recently disappeared from the upstream 4/5 portion of that habitat and now appears restricted to an approximately 17.6 km (11 mi) reach in Jefferson County.

Previous Federal Action

The six aquatic snails were identified as Category 2 species in notices of review published in the **Federal Register** on November 21, 1991 (56 FR 58804), and November 15, 1994 (59 FR 58982). At that time, a Category 2 species was one that was being considered for possible addition to the Federal List of Endangered and Threatened Wildlife, but for which conclusive data on biological vulnerability and threat were not available to support a proposed rule. Designation of Category 2 species was discontinued in the February 28, 1996, Notice of Review (61 FR 7956). The six snails considered in this proposal were approved as Candidate species by the Service on November 9, 1995, and identified as Candidates in the 1996 Notice of Review. A Candidate species is defined as a species for which the Service has on file sufficient information on biological vulnerability and threats to support issuance of a proposed rule.

A status review summary, that included these six snails, was mailed on August 23, 1994 (62 letters), to appropriate species authorities, State and Federal agencies, private organizations, and interested individuals. A cover letter provided notification that a status review was in progress by the Service, stated that the species appeared to qualify for listing under the Act, and requested a review of the status review summary for accuracy regarding taxonomy, distribution, threats, and status. Three species authorities responded by telephone concurring with the status reviews. No other comments were received as a result of this notification.

An updated status report, along with a review request, was mailed on March 11, 1997 (157 letters), following elevation of the snails to Candidate status. One snail authority concurred with the status review analysis; however, he recommended additional genetic studies on the lacy elimia (see *Background* section above). Two other snail authorities responded concurring with the analysis, as well as the taxonomic treatment of the six species.

On September 5, 1995, the Service received two petitions, dated August 31, 1995, from a coalition of environmental organizations (Coosa-Tallapoosa Project, Biodiversity Legal Foundation, and Alabama Wilderness Alliance) represented by Mr. Ray Vaughan. The petitioners requested the Service to list the plicate rocksnail as endangered and to designate critical habitat for this species. The second petition requested the Service to list the lacy elimia as a threatened species and to designate critical habitat.

Section 4 (b)(3)(A) of the Act and implementing regulations at 50 CFR part 424.14 require that, to the extent practicable, the Service make a finding of substantiality on any petition within 90 days of its receipt, and publish a notice of its finding in the **Federal Register**. If a substantial 90-day finding is made, the Service is required, to the

extent practicable, within 12 months of receipt of the petition, to make a finding as to whether the action requested in the petition is (a) not warranted, (b) warranted, or (c) warranted but precluded. Because of budgetary constraints and the lasting effects of a congressionally imposed listing moratorium, the Service is processing petitions and other listing actions according to the listing priority guidance published in the **Federal Register** on December 5, 1996 (61 FR 64475). The guidance clarifies the order in which the Service will process listing actions during fiscal year 1997. The guidance calls for giving highest priority to handling emergency situations (Tier 1) and second highest priority (Tier 2) to resolving the status of outstanding proposed listings. Third priority (Tier 3) is given to resolving the conservation status of Candidate species and processing administrative findings on petitions to add species to the lists or reclassify threatened species to endangered status. The processing of these two petitions and the proposed rule falls under Tier 3. At this time, the Southeast Region has no pending Tier 1 actions and is near completion of its pending Tier 2 actions. Additionally, the guidance states that ''effective April 1, 1997, the Service will concurrently undertake all of the activities presently included in Tiers 1, 2, and 3'' (61 FR 64480). This proposal constitutes the 90-day and 12-month finding on the petitioned actions.

Summary of Factors Affecting the Species

Section 4 of the Act and regulations (50 CFR part 424) promulgated to implement the listing provisions of the Act set forth the procedures for adding species to the Federal lists. A species may be determined to be an endangered or threatened species due to one or more of the five factors described in section 4(a)(1). These factors and their application to the cylindrical lioplax (*Lioplax cyclostomaformis*), flat pebblesnail (*Lepyrium showalteri*), plicate rocksnail (*Leptoxis plicata*), painted rocksnail (*Leptoxis taeniata*), round rocksnail (*Leptoxis ampla*), and lacy elimia (*Elimia crenatella*) are as follows:

A. *The present or threatened destruction, modification, or curtailment of its habitat or range.* The cylindrical lioplax, flat pebblesnail, lacy elimia, round rocksnail, painted rocksnail, and plicate rocksnail have all disappeared from more than 90 percent of their historic ranges. All of these snails were historically, and continue to be, strongly associated with river or stream habitats characterized by flowing currents, and hard, clean bottoms (e.g., bedrock, boulder, gravel) (Goodrich 1922, 1936; Clench and Turner 1955). The curtailment of habitat and range for these six species in the Basin's larger rivers (Coosa, Alabama, Tombigbee and Black Warrior) is primarily due to extensive construction of dams and the inundation of the snail's shoal habitats by impounded waters. Thirty dams have changed this system from a continuum of free-flowing riverine habitats into a series of impoundments connected by short, free-flowing reaches. On the Alabama River there are 3 dams (built between 1968–1971); the Black Warrior has 5 (1915–1959); the Coosa 10 (1914–1966), and the Tombigbee 12 (1954–1979). Dams impound approximately 1,650 km (1,022 mi) of river channel in the Basin.

These six snail species have disappeared from all portions of their historic habitats that have been impounded by dams. As noted earlier, they are all associated with fast currents over clean, hard bottom materials. Dams change such areas by eliminating or reducing currents, and allowing sediments to accumulate on inundated channel habitats. Impounded waters also experience changes in water chemistry which could affect survival or reproduction of riverine snails. For example, many reservoirs in the Basin currently experience eutrophic conditions, including chronically low dissolved oxygen levels (Alabama Department of Environmental Management (ADEM) 1994, 1996). Such physical and chemical changes can affect feeding, respiration, and reproduction of these riffle and shoal snail species.

A site on the Locust Fork River is currently considered for the construction of a water supply impoundment (C. Waldrep, Gorham & Waldrep, P.C., Montgomery, Alabama, *in litt.* 1995). If constructed, this impoundment would bisect and threaten the only single surviving population of the plicate rocksnail. Plicate rocksnails occurred in riffle and shoal habitats above and below the reservoir site in 1994. In 1996, plicate rocksnails could not be relocated in the portion of the river to be flooded by the reservoir; however, they were confirmed to continue to survive in an approximately 17.6 km (11 mi) reach of river below the proposed dam site, which would be subject to impacts from construction activities and post-construction changes in water quality (Garner pers. comm. 1996).

In addition to directly altering snail habitats, dams and their impounded waters also formed barriers to the movement of snails that continued to live below dams or in unimpounded tributaries. It is suspected that many such isolated colonies gradually disappear as a result of local water and habitat quality changes. Unable to emigrate, the isolated snail populations are vulnerable to local discharges as well as any detrimental land surface runoff within their watersheds. Although many watershed impacts have been temporary, eventually improving or even disappearing with the advent of new technology, practices, or laws, dams and their impounded waters prevent natural recolonization by snail populations surviving elsewhere.

Prior to the passage of the Clean Water Act and the adoption of State water quality criteria, water pollution may have been a significant factor in the disappearance of snail populations from unimpounded tributaries of the Basin's impounded mainstem rivers. For example, Hurd (1974) noted the extirpation of freshwater mussel communities from several Coosa River tributaries, including the Conasauga River below Dalton, Georgia, the Chatooga River, and Tallaseehatchee Creek, apparently as a result of textile and carpet mill waste discharges. He also attributed the disappearance of the mussel fauna from the Etowah River, Talladega and Swamp creeks, and from many of the lower tributaries of the Coosa River, to organic pollution and siltation.

Short-term and long-term impacts of point and nonpoint source water and habitat degradation continue to be a primary concern for the survival of all these snails, compounded by their isolation and localization. Point source discharges and land surface runoff (nonpoint pollution) can cause nutrification, decreased dissolved oxygen concentration, increased acidity and conductivity, and other changes in water chemistry that are likely to seriously impact aquatic snails. Point sources of water quality degradation include municipal and industrial effluents.

Nonpoint source pollution from land surface runoff can originate from virtually all land use activities, and may include sediments, fertilizers, herbicides, pesticides, animal wastes, septic tank and gray water leakage, and oils and greases (ADEM 1996). During many recent surveys for these snails, sediment deposition and nutrient enrichment of stream reaches was noted as being associated with the absence of snails from historic collection localities (Bogan and Pierson 1993a, 1993b; Hartfield 1991; Service Field

Observations 1992–1994, Jackson Field Office, MS).

Excessive sediments are believed to impact riverine snails requiring clean, hard shoal stream and river bottoms, by making the habitat unsuitable for feeding or reproduction. Similar impacts resulting from sediments have been noted for many other components of aquatic communities. For example, sediments have been shown to abrade and/or suffocate periphyton (organisms attached to underwater surfaces, upon which snails may feed); affect respiration, growth, reproductive success, and behavior of aquatic insects and mussels; and affect fish growth, survival, and reproduction (Watters 1995).

Sediment is the most abundant pollutant produced in the Basin (ADEM 1989). Potential sediment sources within a watershed include virtually all activities that disturb the land surface, and all localities currently occupied by these snails are affected to varying degrees by sedimentation. The amount and impact of sedimentation on snail habitats may be locally correlated with the land use practice. For example, the use of agriculture, forestry, and construction Best Management Practices can reduce sediment amounts and impacts.

Land surface runoff contributes the majority of human-induced nutrients to water bodies throughout the country (Louisiana Department of Environmental Quality 1995). Excessive nutrient input (from fertilizers, sewage waste, animal manure, etc.) can result in periodic low dissolved oxygen levels that are detrimental to aquatic species (Hynes 1970). Nutrients also promote heavy algal growth that may cover and eliminate clean rock or gravel habitats of shoal dwelling snails. Nutrient and sediment pollution may have synergistic effects on freshwater snails and their habitats, as has been suggested for aquatic insects (Watters 1995).

The cylindrical lioplax, flat pebblesnail, and the round rocksnail currently survive in localized reaches of the Cahaba River drainage. Water quality studies in the upper Cahaba River drainage by the Geological Survey of Alabama (Shepard *et al.* 1996) found that discharges from 34 waste water treatment plants (WWTPs) in the upper drainage have contributed to water quality impairment. This was reflected by low levels of dissolved oxygen downstream of Birmingham; ammonia and chlorination by-products in excess of recommended water quality criteria; and eutrophication due to excessive levels of phosphorus and nitrogen. The study noted that these problems are chronic and have been a factor in a loss of mollusk and fish diversity throughout the drainage. Their results indicate that the upper Cahaba River drainage is primarily impacted by nonpoint runoff and WWTPs through physical habitat destruction by sedimentation, and chronic stress from exposure to toxics and low dissolved oxygen. The middle Cahaba River is primarily impacted by eutrophication and associated affects.

The lacy elimia is now restricted to three small stream channels in Talladega County, Alabama—Cheaha, Emauhee, and Weewoka creeks (Coosa River drainage). The painted rocksnail currently survives in localized reaches of three other Coosa River tributaries, Choccolocco, Buxahatchee, and Ohatchee creeks. The plicate rocksnail inhabits a single short reach of the Locust Fork River in Jefferson County, Alabama (Black Warrior River drainage). All of these streams are variously impacted by sediments and nutrients from a variety of upstream rural, suburban, and/or urban sources. The streams are all small to moderate in size and volumes of flow, and their water and habitat quality can be rapidly affected by local and offsite pollution sources.

Habitat fragmentation and population isolation are a significant threat to the continued survival of the lacy elimia and painted rocksnail. The known populations of these two species are isolated by extensive areas of impoundment, and there is little, if any, possibility of genetic exchange between them. Over time, this isolation may result in genetic drift, with each population becoming unique and vulnerable to environmental disturbance.

B. *Overutilization for commercial, recreational, scientific, or educational purposes.* The six aquatic snail species addressed in this proposed rule are currently not of commercial value, and overutilization has not been a problem. However, as their rarity becomes known, they may become more attractive to collectors. Unregulated collecting by private and institutional collectors poses a threat. The cylindrical lioplax, flat pebblesnail, plicate rocksnail, painted rocksnail, round rocksnail, and lacy elimia inhabit shallow, fast-flowing waters of shoals and riffles. Because of their occurrence and exposure in such areas, they are readily vulnerable to overcollecting and/or vandalism. In these areas, the snails are also exposed to crushing by recreational activities such as canoeing, wading, swimming, or fishing; however, normal recreational activities are not believed to be a factor in their decline.

C. *Disease or predation.* Aquatic snails are consumed by various vertebrate predators, including fishes, mammals, and possibly birds. Predation by naturally occurring predators is a normal aspect of the population dynamics of a species and is not considered a threat to these species. However, the potential now exists for black carp (*Mylopharyngodon piceus*), a nonselective molluskivore recently introduced into waters of the United States, to eventually enter the Mobile River Basin. Exotic black carp recently escaped to the Osage River in Missouri when hatchery ponds were flooded during a 1994 spring flood of the river (LMRCC newsletter, 1994). The extent of stocking black carp for snail control in aquaculture ponds within the Basin is unknown; however, black carp are currently cultured and sold within the State of Mississippi (D. Reike, Mississippi Department of Wildlife, Fisheries, and Parks, 1997).

D. *The inadequacy of existing regulatory mechanisms.* Although the negative effects of point source discharges on aquatic communities have probably been reduced over time by compliance with State and Federal regulations pertaining to water quality, there is currently no information on the sensitivity of the Mobile River Basin snail fauna to common industrial and municipal pollutants. Current State and Federal regulations regarding such discharges are assumed to be protective; however, these snails may be more susceptible to some pollutants than test organisms currently used in bioassays. A lack of adequate research and data currently prevents existing authorities, such as the Clean Water Act (CWA), administered by the Environmental Protection Agency (EPA) and the Army Corps of Engineers, from being fully utilized. The Service is currently working with EPA to develop a memorandum of agreement (MOA) that will address how EPA and the Service will interact relative to CWA water quality criteria and standards within the Service's Southeast Region.

Lacking State or Federal recognition, these snails are not given any special consideration under other environmental laws when project impacts are reviewed.

E. *Other natural or manmade factors affecting its continued existence.* The narrow distribution of extant populations of all six snail species and the nature of their habitats (i.e., small to moderate sized streams) renders them vulnerable to a natural catastrophic event (e.g., flood, drought).

The Service has carefully assessed the best scientific and commercial

information available regarding the past, present, and future threats faced by these species in determining to propose this rule. Based on these evaluations, the preferred action is to list the cylindrical lioplax, flat pebblesnail, and plicate rocksnail as endangered; and the painted rocksnail, round rocksnail, and lacy elimia as threatened. All of these species have been rendered vulnerable due to significant loss of habitat and severe range restriction.

The cylindrical lioplax is confined in distribution to a short reach of the Cahaba River. The flat pebblesnail currently survives in localized portions of the Cahaba River and the Little Cahaba River. Both species are vulnerable to extinction by their confined ranges, and current impacts from water quality degradation in the Cahaba River drainage. The single known population of the plicate rocksnail is threatened by the proposed construction of an impoundment within its remaining habitat in the Locust Fork, and water quality degradation. The plicate rocksnail has also experienced a significant reduction in range within the Locust Fork within the past 2 years, apparently due to pollution of its habitat from nonpoint sources. Endangered status is appropriate for these three species due to their single populations, restricted numbers within these populations, existing threats to their occupied habitats, and in the case of the plicate rocksnail, an ongoing decline in range.

The lacy elimia, painted rocksnail, and round rocksnail are each currently known from three distinct drainage localities. Extant populations and colonies of these three species are localized, isolated, and are vulnerable to water quality degradation, future human activities that would degrade their habitats, and random catastrophic events. Threatened status is considered more appropriate for these species due to the larger number of populations or colonies, and the less immediate nature of these threats.

Critical Habitat

Critical habitat is defined in section 3 of the Act as: (i) the specific areas within the geographical area occupied by a species, at the time it is listed in accordance with the Act, on which are found those physical or biological features (I) essential to the conservation of the species and (II) that may require special management consideration or protection and; (ii) specific areas outside the geographical area occupied by a species at the time it is listed, upon a determination that such areas are essential for the conservation of the species.

Section 4(a)(3) of the Act, as amended, and implementing regulations (50 CFR 424.12) requires that, to the maximum extent prudent and determinable, the Secretary designate critical habitat at the time the species is determined to be endangered or threatened. Service regulations (50 CFR 424.12(a)(1)) state that designation of critical habitat is not prudent when one or both of the following situations exist (1) The species is threatened by taking or other activity and the identification of critical habitat can be expected to increase the degree of threat to the species or (2) such designation of critical habitat would not be beneficial to the species. The Service finds that designation of critical habitat is not presently prudent for any of these six aquatic snails.

Critical habitat designation, by definition, directly affects only Federal agency actions. Since these snail species are aquatic throughout their life cycles, Federal actions that might affect these species and their habitats include those with impacts on stream channel geometry, bottom substrate composition, water quantity and quality, and stormwater runoff. Such activities would be subject to review under section 7(a)(2) of the Act, whether or not critical habitat was designated. Section 7(a)(2) requires Federal agencies to ensure that activities they authorize, fund, or carry out are not likely to jeopardize the continued existence of a listed species or to destroy or adversely modify its critical habitat. The cylindrical lioplax, flat pebblesnail, plicate rocksnail, round rocksnail, painted rocksnail, and lacy elimia have become so restricted in distribution that any significant adverse modification or destruction of their occupied habitats would likely jeopardize their continued existence. This would also hold true as the species recovers and its numbers increase. Therefore, habitat protection for these six species can be accomplished through the section 7 jeopardy standard and there is no benefit in designating currently occupied habitat of these species as critical habitat.

Recovery of these species will require the identification of unoccupied stream and river reaches appropriate for reintroduction. Critical habitat designation of unoccupied stream and river reaches may benefit these species by alerting permitting agencies to potential sites for reintroduction and allow them the opportunity to evaluate projects which may affect these areas. The Service is currently working with the State and other Federal agencies to periodically survey and assess habitat potential of stream and river reaches for listed and candidate aquatic species within the Mobile River basin. This process provides up to date information on instream habitat conditions in response to land use changes within watersheds. Information generated from surveys and assessments is disseminated through Service coordination with other agencies. Should this rule become final, the Service will work with State and Federal agencies, as well as private property owners and other affected parties, through the recovery process to identify stream reaches and potential sites for reintroduction of these species. Thus, the benefit provided by designation of unoccupied habitat as critical will be accomplished more effectively with the current coordination process and is preferable for aquatic habitats which change rapidly in response to watershed land use practices. In addition, the Service believes that any potential benefits to critical habitat designation are outweighed by additional threats to the species that would result from such designation, as discussed below.

Though critical habitat designation directly affects only Federal agency actions, this process can arouse concern and resentment on the part of private landowners and other interested parties. The publication of critical habitat maps in the **Federal Register** and local newspapers, and other publicity or controversy accompanying critical habitat designation may increase the potential for vandalism as well as other collection threats (See Factor B under ''Summary of Factors Affecting the Species''). For example, in 1993 the Alabama sturgeon was proposed for endangered status with critical habitat (59 FR 33148). Critical habitat included the lower portions of the Alabama, Cahaba, and Tombigbee rivers in south Alabama. The proposal generated thousands of comments with the primary concern that the actions would devastate the economy of the State of Alabama and severely impact adjoining States. There were reports from State conservation agents and other knowledgeable sources of rumors inciting the capture and destruction of Alabama sturgeon. A primary contributing factor to this controversy was the proposed designation of critical habitat for the sturgeon.

The six snail species addressed in this proposal are especially vulnerable to vandalism. They all are found in shallow shoals or riffles in restricted stream and river segments. The flat

pebblesnail, plicate rocksnail, round rocksnail, painted rocksnail, and lacy elimia attach to the surfaces of bedrock, cobble, or gravel, while the cylindrical lioplax is found under large boulders. The six species are relatively immobile and unable to escape collectors or vandals. They inhabit remote but easily accessed areas, and they are sensitive to a variety of easily obtained commercial chemicals and products. Because of these factors, vandalism or collecting could be undetectable and uncontrolled. For example, the plicate rocksnail recently disappeared from approximately 80 percent of its known occupied habitat. While the Service has been unable to determine the cause of this decline, the disappearance illustrates the vulnerability of this and the other snail species.

All known populations of these six snail species occur in streams flowing through private lands. The primary threat to all surviving populations appears to be pollutants in stormwater runoff that originate from private land activities (see Factor A). Therefore, the survival and recovery of these snails will be highly dependent on landowner cooperation in reducing land use impacts.

Controversy resulting from critical habitat designation has been known to reduce private landowner cooperation in the management of species listed under the Act (e.g., spotted owl, golden cheeked warbler). The Alabama sturgeon experience suggests that critical habitat designation could affect landowner cooperation within watersheds occupied by these six snails.

Based on the above analysis, the Service has concluded critical habitat designation would provide little additional benefit for these species beyond those that would accrue from listing under the Act. The Service also concludes that any potential benefit from such a designation would be offset by an increased level of vulnerability to vandalism or collecting, and by a possible reduction in landowner cooperation to manage and recover these species. The designation of critical habitat for these six snail species is not prudent.

Available Conservation Measures

Conservation measures provided to species listed as endangered or threatened under the Act include recognition, recovery actions, requirements for Federal protection, and prohibitions against certain practices. Recognition through listing encourages and results in conservation actions by Federal, State, and private agencies, groups, and individuals. The Act provides for possible land acquisition and cooperation with the States and requires that recovery actions be carried out for all listed species. The protection required of Federal agencies and the prohibitions against taking and harm are discussed, in part, below.

Section 7(a) of the Act, as amended, requires Federal agencies to evaluate their actions with respect to any species that is proposed or listed as endangered or threatened and with respect to its critical habitat, if any is being designated. Regulations implementing this interagency cooperation provision of the Act are codified at 50 CFR part 402. Section 7(a)(4) requires Federal agencies to confer informally with the Service on any action that is likely to jeopardize the continued existence of a proposed species or result in destruction or adverse modification of proposed critical habitat. If a species is listed subsequently, section 7(a)(2) requires Federal agencies to ensure that activities they authorize, fund, or carry out are not likely to jeopardize the continued existence of such a species or to destroy or adversely modify its critical habitat. If a Federal action may affect a listed species or its critical habitat, the responsible Federal agency must enter into formal consultation with the Service.

Federal activities that could occur and impact these species include, but are not limited to, the carrying out or the issuance of permits for reservoir construction, stream alterations, discharges, wastewater facility development, water withdrawal projects, pesticide registration, mining, and road and bridge construction. It has been the experience of the Service, however, that nearly all section 7 consultations have been resolved so that the species have been protected and the project objectives have been met. Other than a potential dam on the Locust Fork River, Jefferson and Blount counties, Alabama, no other Federal activities that may affect these species are currently known to be under consideration.

The Act and its implementing regulations found at 50 CFR 17.21 for endangered species, and 17.21 and 17.31 for threatened species set forth a series of general prohibitions and exceptions that apply to all endangered or threatened wildlife. These prohibitions, in part, make it illegal for any person subject to the jurisdiction of the United States to take (includes harass, harm, pursue, hunt, shoot, wound, kill, trap, or collect, or to attempt any of these), import or export, ship in interstate commerce in the course of commercial activity, or sell or offer for sale in interstate or foreign commerce any listed species. It also is illegal to possess, sell, deliver, carry, transport, or ship any wildlife that has been taken illegally. Certain exceptions apply to agents of the Service and State conservation agencies.

Permits may be issued to carry out otherwise prohibited activities involving endangered or threatened wildlife species under certain circumstances. Regulations governing permits are at 50 CFR 17.22 and 17.23 for endangered species and 17.32 for threatened species. Such permits are available for scientific purposes, to enhance the propagation or survival of the species, and/or for incidental take in connection with otherwise lawful activities. For threatened species, there are also permits for zoological exhibition, educational purposes, or special purposes consistent with the purposes of the Act.

It is the policy of the Service published in the **Federal Register** on July 1, 1994 (59 FR 34272), to identify, to the maximum extent practicable, those activities that would or would not constitute a violation of section 9 of the Act if these species are listed. The intent of this policy is to increase public awareness as to the effects of these proposed listings on future and ongoing activities within a species' range.

Activities which the Service believes are unlikely to result in a violation of section 9 for these six snails are:

(1) Existing discharges into waters supporting these species, provided these activities are carried out in accordance with existing regulations and permit requirements (e.g., activities subject to sections 402, 404, and 405 of the Clean Water Act and discharges regulated under the National Pollutant Discharge Elimination System (NPDES)).

(2) Typical agriculture and silviculture practices.

(3) Development and construction activities designed and implemented pursuant to State and local water quality regulations.

(4) Existing recreational activities such as swimming, wading, canoeing, and fishing.

Activities that the Service believes could potentially result in ''take'' of these snails, if they should be listed, include:

(1) The unauthorized collection or capture of the species;

(2) Unauthorized destruction or alteration of the species habitat (e.g., instream dredging, channelization, discharge of fill material);

(3) Violation of any discharge or water withdrawal permit;

(4) Illegal discharge or dumping of toxic chemicals or other pollutants into waters supporting the species.

Other activities not identified above will be reviewed on a case-by-case basis to determine if a violation of section 9 of the Act may be likely to result from such activity should these snails become listed. The Service does not consider these lists to be exhaustive and provides them as information to the public.

Questions regarding whether specific activities may constitute a future violation of section 9 should these snails be listed should be directed to the Field Supervisor of the Service's Jackson Field Office (see **ADDRESSES** section). Requests for copies of regulations regarding listed species and inquiries about prohibitions and permits should be addressed to the U.S. Fish and Wildlife Service, Ecological Services Division, 1875 Century Boulevard, Atlanta, Georgia 30345 (Phone 404/679–7313; Fax 404/679–7081).

Public Comments Solicited

The Service intends that any final action resulting from this proposal will be as accurate and as effective as possible. Therefore, comments or suggestions from the public, other concerned governmental agencies, the scientific community, industry, or any other interested party concerning this proposed rule are hereby solicited. Comments particularly are sought concerning:

(1) biological, commercial trade, or other relevant data concerning any threat (or lack thereof) to this species;

(2) the location of any additional populations of this species and the reasons why any habitat should or should not be determined to be critical habitat as provided by Section 4 of the Act;

(3) additional information concerning the range, distribution, and population size of this species; and

(4) current or planned activities in the subject area and their possible impacts on this species.

Final promulgation of the regulations on these species will take into consideration the comments and any additional information received by the Service, and such communications may lead to final regulations that differ from this proposal.

The Act provides for one or more public hearings on this proposal, if requested. Requests must be received within 45 days of the date of publication of the proposal in the **Federal Register**. Such requests must be made in writing and addressed to the Field Supervisor (see **ADDRESSES** section).

National Environmental Policy Act

The Fish and Wildlife Service has determined that an Environmental Assessment, as defined under the authority of the National Environmental Policy Act of 1969, need not be prepared in connection with regulations adopted pursuant to Section 4(a) of the Act. A notice outlining the Service's reasons for this determination was published in the **Federal Register** on October 25, 1983 (48 FR 49244).

Required Determinations

The Service has examined this regulation under the Paperwork Reduction Act of 1995 and found it to contain no information collection requirements.

References Cited

A complete list of all references cited herein, as well as others, is available upon request from the Field Supervisor (see **ADDRESSES** section).

Author: The primary author of this proposed rule is Paul Hartfield (see **ADDRESSES** section)(601/965–4900, Ext. 25).

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Reporting and recordkeeping requirements, Transportation.

Proposed Regulation Promulgation

Accordingly, the Service hereby proposes to amend part 17, subchapter B of chapter I, title 50 of the Code of Federal Regulations, as set forth below:

PART 17—[AMENDED]

1. The authority citation for part 17 continues to read as follows:

Authority: 16 U.S.C. 1361–1407; 16 U.S.C. 1531–1544; 16 U.S.C. 4201–4245; Pub. L. 99–625, 100 Stat. 3500, unless otherwise noted.

2. Section 17.11(h) is amended by adding the following, in alphabetical order under SNAILS, to the List of Endangered and Threatened Wildlife to read as follows:

§ 17.11 Endangered and threatened wildlife.

* * * * *

(h) * * *

Species		Historic range	Vertebrate population where endangered or threatened	Status	When listed	Critical habitat	Special rules
Common name	Scientific name						
*	*	*	*	*	*	*	
SNAILS							
*	*	*	*	*	*	*	
Elimia, lacy	*Elimia crenatella*	U.S.A. (AL)	NA	T		NA	NA
*	*	*	*	*	*	*	
Lioplax, cylindrical	*Lioplax cyclostomaformis.*	U.S.A. (AL)	NA	E		NA	NA
*	*	*	*	*	*	*	
Pebblesnail, flat	*Lepyrium showalteri*	U.S.A. (AL)	NA	E		NA	NA
*	*	*	*	*	*	*	
Rocksnail, painted	*Leptoxis taeniata*	U.S.A. (AL)	NA	T		NA	NA
*	*	*	*	*	*	*	
Rocksnail, plicate	*Leptoxis plicata*	U.S.A. (AL)	NA	E		NA	NA
*	*	*	*	*	*	*	
Rocksnail, round	*Leptoxis ampla*	U.S.A. (AL)	NA	T		NA	NA

Species		Historic range	Vertebrate population where endangered or threatened	Status	When listed	Critical habitat	Special rules
Common name	Scientific name						
*	*	*	*	*	*		*

Dated: September 12, 1997.

Jamie Rappaport Clark,

Director, Fish and Wildlife Service.

[FR Doc. 97–27548 Filed 10–16–97; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

RIN 1018–AE41

Endangered and Threatened Wildlife and Plants; Proposal to List the St. Andrew Beach Mouse as Endangered

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule.

SUMMARY: The Fish and Wildlife Service (Service) proposes endangered status for the St. Andrew Beach Mouse (*Peromyscus polionotus peninsularis*) pursuant to the Endangered Species Act of 1973, as amended (Act). This subspecies is restricted to coastal sand dunes and had a historic distribution that included the northeast Florida panhandle from Gulf County into portions of Bay County. Its current range is limited to a portion of the St. Joseph Peninsula in Gulf County. Habitat impacts causing loss of mice and the species' local capability to recover from such impacts are primarily responsible for the range curtailment. Threats to beach mouse habitat include severe storms, coastal land development and its associated activities, and non-storm related, natural shoreline erosion. Additional threats include predation by free-ranging domestic cats and displacement by house mice. This proposal, if made final, would implement the protection provisions provided by the Act for this beach mouse.

DATES: Comments from all interested parties must be received by December 16, 1997. Public hearing requests must be received by December 1, 1997.

ADDRESSES: Comments and materials concerning this proposal should be sent to Michael M. Bentzien, Assistant Field Supervisor, U.S. Fish and Wildlife Service, 6620 Southpoint Drive South, Suite 310, Jacksonville, Florida 32216. Comments and materials received will be available for public inspection, by appointment, during normal business hours at the above address.

FOR FURTHER INFORMATION CONTACT: Dr. Michael M. Bentzien, at the above address (telephone 904/232–2580, ext. 106; facsimile 904/232–2404).

SUPPLEMENTARY INFORMATION:

Background

The oldfield mouse (*Peromyscus polionotus*) occurs in northeastern Mississippi, Alabama, Georgia, South Carolina, and Florida. Beach mice are coastal subspecies of the oldfield mouse restricted to beach and sand dune habitat. Hall (1981) recognized eight coastal subspecies whose common distinguishing characteristics include white feet, large ears, and large black eyes. Their fur is variously patterned in shades of white, yellow, brown, and grey. The head, back, and rump are darkly patterned, though to a lighter and less extensive degree than inland oldfield mice. The all-white underparts extend higher up to the sides than on the inland subspecies (Sumner 1926, Bowen 1968). Howell (1939) described the type (original) specimen of the St. Andrew beach mouse as having a very pale, buff-colored head and back with extensive white coloration underneath and along the sides. Bowen (1968) noted two distinct rump color pigmentations, one a tapered and the other a squared pattern, which extended to the thighs. Head and body lengths average 75 millimeters (mm) (2.95 inches (in)), tail mean length 52 mm (2.05 in), and hind foot mean length 18.5 mm (0.73 in) (James 1992).

Beach mice subspecies historically occurred on both the Atlantic Coast of Florida from St. Johns through Broward counties and the eastern Gulf of Mexico from Gulf County, Florida, to Baldwin County, Alabama (Ivey 1949, Bowen 1968, James 1992, Stout 1992, Gore and Schaefer 1993). The St. Andrew beach mouse is the easternmost of the five Gulf coast subspecies. Howell (1939) collected the type specimen at St. Andrew Point on Crooked Island, Tyndall Air Force Base, Bay County, Florida (type locality). Other historic collection records for the subspecies include nine additional specimens from the type locality, seven mice from St. Joseph Point and four mice from Cape San Blas on the St. Joseph Peninsula in Gulf County, 48 individuals at or near the town of Port St. Joe located on the central Gulf County coastal mainland, and four specimens near Money Bayou in eastern Gulf County (Bowen 1968). Based on these records, Bowen (1968) and James (1992) described the former range of the St. Andrew beach mouse as likely extending from the St. Joseph Spit (Peninsula) northwest along the coastal mainland adjacent to St. Joseph Bay, to Crooked Island at the East Pass of St. Andrews Bay. This range also included about 0.6 kilometer (km) (1 mile (mi)) of mainland sand dune habitat east of the landward end of the St. Joseph Peninsula to Money Bayou on the Gulf of Mexico. The absence of past collection records and lack of beach mouse sign and trapping success in the area east of Money Bayou to the southeastern corner of Gulf County (James 1987; J. Gore, Florida Game and Fresh Water Fish Commission, in litt. 1994) suggest that this area may not be part of the subspecies' historic range.

Coastal tidal marsh and upland habitat between the mainland city of Port St. Joe and the St. Joseph Peninsula naturally divided the former range of the St. Andrew beach mouse into two segments. Initial genetic analysis of a small sample of mice from these segments and another subspecies, the Choctawhatchee beach mouse (*P. polionotus allophrys*), from nearby habitat found similarities between the Crooked Island and St. Joseph Peninsula samples at one gene location (locus). The Crooked Island sample was distinctly different from the Choctawhatchee beach mouse sample at the same locus. Additional work is needed to determine if these patterns are consistent at several loci (Moyers 1997).

Typical beach mouse habitat generally consists of several rows of sand dunes paralleling the shoreline. Prevailing wind, beach sand, and vegetation combine to form and shape coastal dunes. A common complex of animal species, vegetation, and habitat types characterize the coastal sand dune ecosystem. The types and amount of animals, vegetation, and habitat may differ, however, among specific sites. The common types of sand dune habitat include frontal dunes, primary dunes, secondary dunes, inter and intradunal swales, and scrub dunes. Frontal dunes and primary dunes are those closest to

the shoreline, most recently formed, and highly dynamic. The foreslope of primary dunes grades into the developing frontal dunes on the open beach. Frontal dunes on the Gulf Coast are sparsely vegetated, usually by sea oats (*Uniola paniculata*), bluestem (*Schizachyrium maritimum*), beach grass (*Panicum amarum*), and sea rocket (*Cakile constricta*). Primary dunes also support stands of these species and include other broad-leaved plants such as seaside pennywort (*Hydrocotyle bonariensis*), seashore elder (*Iva imbricata*), and beach morning glory (*Ipomea stolonifera*) (Clewell 1985). Secondary dunes consist of one or more dune lines landward of the primary dune with a similar though denser vegetative cover. Interdunal swales are wet or dry depressions between primary and secondary dunes while intradunal swales occur within primary dunes as a result of wave action, storm surges, and wind erosion. Wet swales are those whose water table is at or near the surface. Swale vegetation includes plants found on primary and secondary dunes as well as salt meadow cordgrass (*Spartina patens*), rushes (*Juncus* sp.), sedges (*Cyperus* sp.), and saltgrass (*Distichlis spicata*). Scrub dunes are the oldest of the dune habitat types and are dominated by woody plants including saw palmetto (*Serenoa repens*), myrtle oak (*Quercus myrtifolia*), sand live oak (*Q. geminata*), sand pine (*Pinus clausa*), slash pine (*P. elliottii*), seaside rosemary (*Ceratiola ericoides*), greenbrier (*Smilax* sp.), and bush goldenrod (*Chrysoma pauciflosculosa*). Reindeer moss (*Cladonia leporina*) often covers otherwise bare dune surfaces. Some primary and secondary dune vegetation is also present but at reduced densities (Blair 1951, Gibson and Looney 1992). Size and density of understory and overstory vegetation may vary.

Trap surveys at Crooked Island and on the St. Joseph Peninsula documented the presence of St. Andrew beach mouse on frontal dunes, as well as on primary and secondary dunes (James 1987; Gore in litt. 1990, 1994; Bates 1992, Moyers *et al.* 1996, Mitchell *et al.* 1997). These results supported other surveys which found that the greatest concentration of most other beach mice subspecies occurred in these habitat types (Blair 1951, Hill 1989, Frank and Humphrey 1992, Holler 1992). This concentration is due in part to a predominance of plants whose seeds and fruits are important seasonal constituents of beach mouse diets (Moyers 1996).

Although beach mice occur on interdunal and intradunal swales, studies of other beach mouse subspecies indicate that, in general, they use this habitat type less frequently when compared to frontal, primary, and secondary dunes (Blair 1951, Hill 1989, Gore and Schaefer 1993, Novak 1997). James (1987) only rarely observed St. Andrew beach mouse tracks in the interdunal areas within St. Joseph Peninsula State Park (SJPSP), located within the northern 15 km (9 mi) of the peninsula.

Various researchers have also documented the occurrence of other beach mouse subspecies within scrub dunes (Extine and Stout 1987, Hill 1989, Rave and Holler 1992, Gore and Schaefer 1993, Swilling *et al.* 1996, Moyers *et al.* 1996, Novak 1997). Blair (1951) believed that the scrub dunes on Santa Rosa Island offered abundant food and cover for the Santa Rosa beach mouse (*P. p. leucocephalus*). Scrub dunes may also function as refugia during and after storms and as a source for recolonization of storm-damaged dunes (Moyers *et al.* 1996, Swilling *et al.* 1996). Their use by the St. Andrew beach mouse is not well documented. James (1987) noted the absence of tracks in scrub dunes within SJPSP, although she did collect mice in 1986 from well-vegetated back dunes on Crooked Island (James 1992). Moyers *et al.* (1996) captured beach mice within SJPSP in secondary dunes immediately adjacent to scrub dunes.

Based on a study of other Gulf coast subspecies that included habitat conditions following Hurricane Frederick, Meyers (1983) reported that the minimum post-storm area needed to allow beach mice to persist was 50 hectares (ha) (124 acres (ac)). He also determined that a habitat size from 100 to 200 ha (247 to 494 ac) supporting a population of 127 mice was optimal for that population to recover from habitat impacts produced by a storm of comparable intensity. Meyer's figures should be used with caution, however, since he did not know pre-storm habitat conditions or population numbers within the study area.

Beach mouse populations can at times undergo great seasonal variations in numbers (Bowen 1968, Extine and Stout 1987). Prior to human disturbance, hurricanes and tropical storms likely were the dominant factors producing rapid and possible widespread impacts on beach mice and their habitat. Because the St. Andrew beach mouse evolved under adverse weather conditions, the subspecies developed the capability to survive and recover from these periodic severe impacts to its numbers and habitat. During this century, however, more rapid land development, dune encroachment by pedestrians and vehicles, and military activities began to contribute to these impacts (James 1992). Bowen (1968) was unable to collect beach mice from one or more historic sites during a 1961 field trip. Hurricane Eloise split Crooked Island into east and west segments in 1975, and multiple attempts to collect beach mice from the western segment during the early and mid-1980's were unsuccessful (Gore in litt. 1987). During this same period, trap surveys collected small numbers of beach mice on the eastern segment. Limited trap and track surveys during the late 1980's found no evidence of beach mice within undeveloped coastal mainland habitat between Crooked Island and Money Bayou, as well as on the St. Joseph Peninsula from near the southern border of SJPSP through Cape San Blas to the northeastern end of the peninsula (Gore in litt. 1990, James 1987). Both surveys revealed that mice still existed on Crooked Island East and also occurred within SJPSP. Gore collected 3.6 mice per 100 trap nights during his 1989 survey within the park. Based on her survey results, James (1992) estimated the Crooked Island East population at 150 mice and the population within SJPSP at 500 mice. Gore speculated that the range wide population at its lowest contained several hundred mice.

Extensive surveying of primary, secondary, and scrub dune habitat on Crooked Island East during the 1990's revealed that the beach mouse population there no longer existed (Gore in litt. 1994, Holler in litt. 1994). Similar efforts at Cape San Blas on Eglin Air Force Base and U.S. Coast Guard properties yielded no mice (Gore in litt. 1994). Bates (1992) did capture 338 separate individuals within SJPSP at a rate of 26.64 mice per 100 trap nights. In 1993 and 1994, Gore (in litt. 1994) again sampled habitat between SJPSP and Cape San Blas and trapped nine beach mice for a capture rate of 7.56 mice per 100 trap nights. Based on the survey findings to date, Gore (in litt 1994, 1995) assumed that the St. Andrew beach mouse was then restricted to the northern 20 to 25 km (12.5 to 15.5 mi) of the St. Joseph Peninsula.

In October 1995, Hurricane Opal caused extensive coastal damage to the Florida panhandle. Habitat impacts within the St. Joseph Peninsula appeared more extensive outside SJPSP boundaries (Gore in litt. 1995). Using an average density estimate of 2.5 mice per hectare, Gore (in litt. 1995) calculated that the total population of St. Andrew beach mice remaining after the storm was around 190 individuals. Moyers *et al.* (1996) trapped a total of about 5.25 km (3 mi) of habitat throughout SJPSP

in December 1995 and captured 62 individuals for a rate of 3.44 mice per 100 trap nights. They estimated the population size within the sampled area at 127, a figure which compared favorably to Gore's post-hurricane estimate. Moyers (1996a) later collected an additional 11 mice on William J. Rish State Park and on some private parcels within the St. Joseph Peninsula immediately south of SJPSP. The most recent trap survey within SJPSP (February 1997) collected 117 mice for a capture rate of 9.00 mice per 100 trap nights (Mitchell *et al.* 1997). They estimated that SJPSP currently may support between 300 and 500 mice. The estimate represents a significant increase over the 1995 post-Hurricane Opal survey and is comparable to the last pre-Hurricane Opal survey within the park (Bates 1992).

In addition to habitat impacts, other factors believed to potentially threaten the continued existence of the St. Andrew beach mouse are predation, particularly by free-ranging domestic cats (*Felis silvestris*) and non-native coyotes (*Canis latrans*), and displacement by house mice (*Mus musculus*).

Previous Federal Action

The Service included the St. Andrew beach mouse as a category 2 species in its September 18, 1985, notice of review of vertebrate wildlife (50 FR 37958). At that time, category 2 species were defined as those for which information in possession of the Service indicated that proposing to list as endangered or threatened was possibly appropriate, but for which conclusive data on biological vulnerability and threat(s) were not currently available to support a proposed rule. The Service published an updated, combined animal notice of review (ANOR) on January 6, 1989, which retained the species' category 2 classification (54 FR 554). In the November 21, 1991, ANOR update, the St. Andrew beach mouse was designated a candidate for listing (56 FR 58804). The Service retained this classification in the November 15, 1994, ANOR (59 FR 59020) and in the most recent notice of review published on February 28, 1996 (61 FR 7596).

The processing of this proposed rule conforms with the Service's fiscal year 1997 listing priority guidance published in the **Federal Register** on December 5, 1996 (61 FR 64475). The guidance calls for giving highest priority to handling emergency situations (Tier 1) and second highest priority (Tier 2) to resolving the status of outstanding proposed listings. Third priority (Tier 3) is given to resolving the conservation status of candidate species and processing administrative findings on petitions to add species to the lists or reclassify threatened species to endangered status. The processing of this proposed rule falls under Tier 3. At this time, the Southeast Region has no pending Tier 1 actions and is near completion of its pending Tier 2 actions. Additionally, the guidance states that ''effective April 1, 1997, the Service will concurrently undertake all of the activities included in Tiers 1, 2, and 3'' (61 FR 64480).

Summary of Factors Affecting the Species

Section 4 of the Endangered Species Act and regulations (50 CFR part 424) promulgated to implement the listing provisions of the Act set forth the procedures for adding species to the Federal lists. A species may be determined to be an endangered or threatened species due to one or more of the five factors described in section 4(a)(1). These factors and their application to the St. Andrew beach mouse (*Peromyscus polionotus peninsularis*) are as follows:

A. The Present or Threatened Destruction, Modification, or Curtailment of Its Habitat or Range

Using historic topographic maps and their habitat references, the Service calculated that 66 km (41 mi) of the estimated 86 km (53.5 mi) of linear area within the historic range of the St. Andrew beach mouse contained sand dune habitat. From field surveys, Gore (in litt. 1994, 1995) estimated the amount of recently occupied habitat to be between 20 and 23 km (14.3 to 12.5 mi), all within the northern two-thirds of the St. Joseph Peninsula. This represents up to a 68 percent curtailment of historic sand dune habitat within the subspecies' former range.

Natural events and manmade activities that have impacted the St. Andrew beach mouse and its habitat include severe storms, land development, military exercises on Crooked Island, dune encroachment by vehicles and pedestrians, and non-storm related shoreline erosion. Between 1871 and 1995, nearly 50 hurricanes or tropical storms occurred within 90 mi of St. Joe Bay, which is about midway within the historic range of the species. In this century, storm strength, proximity to the historic range, and degree of habitat impact have been especially intense during the last 30 years (Doehring *et al.* 1994). In 1975, Hurricane Eloise breached Crooked Island, dividing it into two segments and severely eroding and fragmenting dunes, particularly within the newly-formed western segment (R. Bates, pers. comm. 1995). In 1985, Hurricane Kate scoured dunes within the entire range of the St. Andrew beach mouse. These storms caused extensive blowouts in the high dunes throughout the St. Joseph Peninsula (James 1992). In 1995, Hurricane Opal, which made landfall 85 mi west of St. Joe Bay, severely damaged and fragmented frontal and primary sand dunes within the historic range of the beach mouse. The most seriously impacted areas were the unoccupied habitat from Crooked Island to Mexico Beach. Gore (in litt. 1995) estimated an average loss of 52 percent of occupied area within the St. Joseph Peninsula, with the greatest impacts occurring south of SJPSP. Although the population within the SJPSP has since recovered, the Service believes that, coupled with additional land development, consecutive years of severe weather or a single season of intense storms over or in close proximity to currently occupied habitat may result in extinction of the subspecies.

Land development has been primarily responsible for the permanent loss of St. Andrew beach mouse habitat. Historic maps suggest that earlier construction of State Road 98 and incorporated development from the vicinity of Port St. Joe to Mexico Beach occurred within one or more types of coastal sand dune habitat. Little or no suitable habitat currently occurs at the seaward side of some of these incorporated areas (J. Danford, Gulf County Division of Solid Waste, pers. comm. 1997). This density of development also tends to fragment remaining undeveloped habitat. Meyers (1983) believed that intense development could act as a barrier to migration, isolating mice within these habitat segments and making them more vulnerable to local extinction from one or more threats. Neither Gore (in litt. 1990) nor James (1987) found evidence of beach mice within these fragmented parcels located along the coast between Port St. Joe and Mexico Beach. The current status of beach mice within these parcels is unknown.

Gore (in litt. 1994) ranked continued habitat loss on the St. Joseph Peninsula as one of the most serious long-term threats to the St. Andrew beach mouse outside of the State parks. He attributed beach mouse presence in the area between SJPSP and Cape San Blas in 1994 to the relatively low density of housing compared to mainland areas, and the apparent low threat from free-ranging domestic cats, which he believed was related to the primary use

of the residences as vacation homes. In addition, most structures are set back from the frontal and primary dune lines. Since 1994, additional construction has occurred in this area, as well as within unoccupied habitat on the remainder of the peninsula (J. Danford, pers. comm. 1997). The construction has proceeded despite the unavailability of federally financed loans or flood insurance (see factor D). The Service believes that continued construction may result in intense development of secondary and scrub dunes, resulting in the severe fragmentation or loss of these habitat types. These areas are known to be important to other beach mice subspecies (see ''Background'' section). Intense impacts to these habitat types, coupled with severe storms affecting frontal and primary dunes, may contribute to the extinction of the St. Andrew beach mouse. Gulf County has constructed snow fencing and planted dune vegetation to restore frontal and primary dunes on the St. Joseph Peninsula and elsewhere damaged as a result of Hurricane Opal (J. Danford, pers. comm. 1997).

Other human activities impact beach mouse habitat. Gore (in litt. 1994) described the sand dunes east of Cape San Blas as having little vegetation and generally in poor quality. He attributed this situation to a combination of storm damage exacerbated by vehicular traffic on the beach. Although Gulf County has updated its beach driving ordinance in an attempt to eliminate dune impacts on the St. Joseph Peninsula (Gulf County Commission 1997), some areas continue to have problems with dune encroachment by all-terrain vehicles (D. Wibberg, Office of the Gulf County Board of Commissioners, pers. comm. 1997). Prior to 1985, trial exercises with military hovercraft contributed to habitat degradation on Crooked Island (James 1992). The Department of Defense has since discontinued this practice (R. Bates, Tyndall Air Force Base, pers. comm. 1995) and is restoring dune habitat and funding translocation of beach mice onto Crooked Island.

Severe natural erosion within a section of beach north of Cape San Blas, primarily within U.S. Coast Guard property on the St. Joseph Peninsula, has resulted in the loss of frontal, primary, and secondary dunes (Gore in litt. 1994). Sporadic natural shoreline erosion of frontal and primary dunes is also occurring north of this area to SJPSP, as well as between Cape San Blas and Money Bayou. The principal effect in the area of severe erosion has been to isolate occupied habitat on the northern peninsula from unoccupied habitat between Cape San Blas and Money Bayou. The additional natural erosion has resulted in some habitat fragmentation.

B. Overutilization for Commercial, Recreational, Scientific, or Educational Purposes

This factor is not now known to be applicable.

C. Disease or Predation

The impact of parasites and pathogens on beach mice populations and their potential contribution to the decline of the St. Andrew beach mouse are unknown. Significant adverse impacts from these factors might occur when combined with or as a function of other threats. Studies and observations by various researchers strongly suggest that predation, especially by free-ranging domestic cats, is an important factor contributing to the loss of mice from local habitat within or adjacent to developed areas (Blair 1951, Humphrey and Barbour 1981, Holliman 1983, Humphrey *et al.* 1987). Bowen (1968) provided an anecdotal report on the complete absence of beach mouse sign on a 3.2 km (2 mi) stretch of beach having abundant cat tracks. Frank and Humphrey (1992) noted a reduction of cat sign on dunes and an increase in Anastasia Island beach mouse (*P. p. phasma*) numbers and mean survivorship following removal of 15 to 20 cats from the camping area at Anastasia State Recreation Area. Gore and Schaeffer (1993) found a significant inverse relationship between the ratio of Santa Rosa beach mice to cat tracks on sample transects within developed and undeveloped dune areas on Santa Rosa Island. Their median transects in the developed areas contained no mouse tracks and 13 cat tracks. Bates (1992) found that predators in SJPSP did not appear to concentrate near dunes and the infrequent house cat tracks observed occurred mainly near structures. Although Bates failed to capture beach mice in dunes adjacent to the camping areas, Moyers *et al.* (1996) did capture mice and observe tracks in these areas. Gore (in litt. 1994) believed that the house cat population then on private lands south of SJPSP was less of a problem than other developed areas because the residences there served mainly as seasonal vacation homes. He nevertheless believed further introductions associated with additional land development could pose a serious threat to beach mouse populations.

Other mammalian predators occurring on sand dunes within SJPSP include fox, bobcat, raccoon, and coyote (Bates 1992). Coyotes are relatively recent migrants to SJPSP and Crooked Island, where they have become predators on sea turtle nests (S. Shea, Tyndall Air Force Base, pers. comm. 1994; J. Bente, Florida Department of Environmental Protection, pers. comm. 1995).

D. The Inadequacy of Existing Regulatory Mechanisms

The Federal Coastal Barrier Resources Act of 1982 and the Coastal Barrier Improvement Act of 1990 (CBRA) prohibit most new Federal expenditures and financial assistance within Coastal Barrier Resources System (CBRS) units. CBRA also prohibits the sale of new Federal flood insurance for new construction or substantial improvements within otherwise protected areas. There are two CBRS units and one otherwise protected area within the historic range of the St. Andrew beach mouse. The Cape San Blas Unit (P30) covers all of the St. Joseph Peninsula, while the otherwise protected area (P30P) corresponds with the boundaries of St. Joseph Peninsula State Park. Habitat west of the city of Mexico Beach, including Crooked Island East and West, are part of the St. Andrew Complex Unit (P31). CBRA does not prohibit use of non-Federal or private funds to finance or insure projects within CBRS units or otherwise protected areas. As a result, coastal construction may still proceed within all remaining undeveloped parcels within the subspecies' historic range.

Eglin Air Force Base currently allows beach driving through its Cape San Blas property and adjacent property it leases from and manages for the U.S. Coast Guard. However, the agreement with Gulf County prohibits vehicles and pedestrians from encroaching on or near sand dunes. Strict enforcement of this provision has been difficult due to the distance of Eglin's main base from the Cape San Blas unit and the lack of onsite enforcement personnel. The distance also hampers efforts at evaluating and taking action on potential problems associated with free-ranging domestic cats.

State laws protect sea oats, a critical component of the dune vegetative community, from being picked on public land but do not prohibit this activity on private land nor their destruction during construction activities. State-regulated Coastal Construction Control Lines (CCCL) correspond to the limits of the coastal high hazard 100-year storm event impact area. Construction seaward of the CCCL requires permits whose stringent requirements generally result in protection of beach, frontal dune, and primary dune habitats (G. Chelicki, Florida Department of Environmental

Protection, pers. comm. 1997). The same protections are not afforded to secondary and scrub dune habitats occurring landward of the CCCL. The State has designated Crooked Island East and West as critical wildlife areas, which would protect plants and animals from take or disturbance by pedestrians, vehicles, and dogs, but this designation does not address habitat protection (S. Shea in litt. 1997).

The St. Andrew beach mouse is listed as a State endangered species. Chapter 39–27.002 of the Florida Administrative Code prohibits the take, possession, or sale of endangered species except as authorized by specific permit for the purpose of enhancing the survival potential of the species. The law does not provide for the protection or conservation of a listed species' habitat.

Bay County, Florida, restricts beach driving to permitted vendors. State parks on the St. Joseph Peninsula do not permit beach driving within their boundaries. Gulf County regulates beach driving on the peninsula between Indian Pass and SJPSP by ordinance and permits. The ordinances restrict the number of vehicle access points and prohibits driving in, on, or over sand dunes or vegetated areas. They do not address pedestrian encroachment. The most recent revised ordinance creates a 7.6 meter (25 foot) dune buffer zone within a portion of the St. Joseph Peninsula, in which beach driving and parking are prohibited (Misty Nabers, Florida Department of Environmental Protection, pers. comm. 1997). This revision does not apply to the section of the peninsula between about 3.2 km (2 mi) northwest of Cape San Blas to Money Bayou (D. Wibberg, pers. comm. 1997).

Gulf County does not have any ordinances relating to the ownership, control, and handling of free-ranging domestic cats.

E. Other Natural or Manmade Factors Affecting its Continued Existence

In addition to severe storms, other widespread climatic conditions that can occur within the range of the St. Andrew beach mouse include periods of drought and freezing weather. The extent of any direct or indirect impacts of these factors on beach mouse survival, either alone or in combination with manmade threats, is not known.

Storms and residential and commercial development can fragment and isolate beach mouse habitat. This isolation precludes movement and gene flow among other habitat blocks. In smaller blocks, the lack of gene flow may result in a loss of genetic diversity, which can reduce the population's fitness. Increased predation pressure and competition for available food and cover may further weaken populations through direct mortality and reduced reproductive success. The combined threats may result in severe decline leading to extinction of these isolated populations (Caughley and Gunn 1996).

The ecological similarity of house mice and oldfield mice (Gentry 1966, Briese and Smith 1973) suggests that competition and aggression may occur between these species. An inverse relationship appears to exist between the population densities of the house mouse and inland oldfield mice (Caldwell 1964, Caldwell and Gentry 1965, Gentry 1966). Humphrey and Barbour (1981) documented mutually exclusive distribution patterns of house mice and other Gulf coast beach mice, a pattern similar to that observed by Frank and Humphrey (1992) for the Anastasia Island beach mouse, and by Gore (in litt. 1987, 1990, 1994) and Holler (in litt. 1994) for the St. Andrew beach mouse. The significance of competition to the observed patterns is not clear. In general, the observations suggest that where conditions favor one of the two species, that species will predominate or exclude the other species. Briese and Smith (1973) noted that house mice primarily invade disturbed areas, such as when development occurs, and are able to establish themselves in these and adjacent habitats occupied by low densities of oldfield mice. They also noted that house mice seem to be less affected by predation from house cats than oldfield mice.

The Service has carefully assessed the best scientific and commercial information available regarding the past, present, and future threats faced by this species in determining to propose this rule. Based on this evaluation, the preferred action is to list the St. Andrew beach mouse (*Peromyscus polionotus peninsularis*) as endangered. The primary threats to the continued existence of the species are habitat impacts from periodic severe weather and land development, which result in direct loss of mice and the capability of remaining mice to recover from such impacts. Other potentially significant threats include predation by free-ranging domestic cats and possible competitive displacement by the house mouse. The Service considers the threat of extinction of high magnitude and imminent because of the more than two-thirds estimated range curtailment, the species' restriction to a single land unit, and the recent high frequency of severe storms occurring within or in close proximity to the species' historic range.

Critical Habitat

Critical habitat is defined in section 3 of the Act as: (i) The specific areas within the geographical area occupied by a species, at the time it is listed in accordance with the Act, on which are found those physical or biological features (I) essential to the conservation of the species and (II) that may require special management considerations or protection; and (ii) specific areas outside the geographical area occupied by a species at the time it is listed, upon a determination that such areas are essential for the conservation of the species. ''Conservation'' means the use of all methods and procedures needed to bring the species to the point at which listing under the Act is no longer necessary.

Section 4(a)(3) of the Act, as amended, and implementing regulations (50 CFR 424.12) require that, to the maximum extent prudent and determinable, the Secretary designate critical habitat at the time the species is determined to be threatened or endangered. The Service finds that designation of critical habitat is not prudent for the St. Andrew beach mouse at this time. Service regulations (50 CFR 424.12(a)(1)) state that designation of critical habitat is not prudent when one or both of the following situations exist—(1) The species is threatened by taking or other human activity, and identification of critical habitat can be expected to increase the degree of threat to the species, or (2) such designation of critical habitat would not be beneficial to the species.

Designated critical habitat is protected by the Act only under section 7(a)(2), which provides that activities that are federally funded, permitted, or carried out may not destroy or adversely modify critical habitat. However, section 7(a)(2), which also prohibits Federal activities likely to jeopardize listed species, provides substantial protection to the habitat of listed species, even if critical habitat is not designated. Section 7(a)(4) requires Federal agencies to confer informally with the Service on any action that is likely to jeopardize the continued existence of a proposed species or result in the destruction or adverse modification of proposed critical habitat. For most species, including the St. Andrew beach mouse, the protection afforded the species' habitat through application of the no jeopardy standard is so strong, the Service believes there would be no direct net conservation benefit from designating critical habitat.

Regulations (50 CFR part 402.02) define ''jeopardize the continued

existence of'' as meaning to engage in an action that would reasonably be expected, directly or indirectly, to reduce appreciably the likelihood of both the survival and recovery of a listed species in the wild by reducing the reproduction, numbers, or distribution of that species. ''Destruction or adverse modification'' is defined as a direct or indirect alteration that appreciably diminishes the value of critical habitat for both the survival and recovery of a listed species. The St. Andrew beach mouse is restricted to coastal sand dunes that consist of several rows paralleling the shoreline. The common types of sand dune habitat include frontal dunes, primary dunes, secondary dunes, inter and intradunal swales, and scrub dunes. Beach mice occur mostly in frontal, primary, and secondary dunes due in part to the predominance of plants whose seeds and fruits are important seasonal constituents of beach mouse diets. Further, scrub dunes may function as refugia during and after storms and as a source for recolonization of storm-damaged dunes. Because of the highly precarious status of the St. Andrew beach mouse, destruction or adverse modification of any of these habitat features to the point of appreciably diminishing habitat value for recovery and survival would also jeopardize the species' continued existence by reducing its reproduction, numbers, or distribution.

For the St. Andrew beach mouse, the Service, therefore, has determined that designation of critical habitat would not add any protection over that afforded by the jeopardy standard. Any appreciable diminishment of habitat sufficient to appreciably reduce the value of the habitat for survival and recovery would also appreciably reduce the likelihood of survival and recovery by reducing reproduction, numbers, or distribution. The Service has found this to be the case for several listed species, for which an appreciable reduction in habitat value would trigger the jeopardy standard, for example the Appalachian elktoe mussel, listed as endangered on November 23, 1994 (59 FR 60324), and three Texas aquatic invertebrates, listed as endangered on June 5, 1995 (60 FR 29537).

Within unoccupied lands under Federal management, both Eglin and Tyndall Air Force bases are actively involved in conservation of sand dune habitat. Eglin Air Force Base does not allow dune encroachment by vehicles and pedestrians within its Cape San Blas unit boundaries and closely reviews mission-related activities for potential habitat impacts (R. McWhite, Eglin Air Force Base, pers. comm. 1997). Eglin recently completed an ecological survey of Cape San Blas that will assist them in deciding how best to manage the natural resources within the unit. On Crooked Island, Tyndall Air Force Base restricts beach access on both east and west segments to pedestrians and authorized vehicles, and also prohibits dune encroachment. Natural resource personnel review all requests for military operations to minimize or eliminate potential habitat disturbances. Because of these current conditions, the Service believes that a designation of Crooked Island or Cape San Blas as critical habitat is not prudent because it would not result in any additional benefit to the species.

Based on the above discussion, the Service has determined that the lack of additional conservation benefit from critical habitat designation for this species makes such designation not prudent.

Available Conservation Measures

Conservation measures provided to species listed as endangered or threatened under the Endangered Species Act include recognition, recovery actions, requirements for Federal protection, and prohibition against certain practices. Recognition through listing results in public awareness and conservation actions by Federal, State, and local agencies, private organizations, and individuals. The Act provides for possible land acquisition and cooperation with the States and requires that recovery actions be carried out for all listed species. The protection required of Federal agencies and the prohibitions against taking and harm are discussed, in part, below.

Section 7(a) of the Act, as amended, requires Federal agencies to evaluate their actions with respect to any species that is proposed or listed as endangered or threatened and with respect to its critical habitat if any is being designated. Regulations implementing this interagency cooperation provision of the Act are codified at 50 CFR part 402. Section 7(a)(4) requires Federal agencies to confer with the Service on any action that is likely to jeopardize the continued existence of a species proposed for listing or result in the destruction or adverse modification of proposed critical habitat. If a species is listed subsequently, section 7(a)(2) requires Federal agencies to ensure that activities they authorize, fund, or carry out are not likely to jeopardize the continued existence of the species or destroy or adversely modify its critical habitat. If a Federal action may affect a listed species or its critical habitat, the responsible Federal agency must enter into formal consultation with the Service.

Federal agency actions that are expected to require conference and/or consultation as described in the preceding paragraph include mission-related activities authorized or carried out by Tyndall Air Force Base on Crooked Island and by Eglin Air Force Base at the Cape San Blas unit, following any translocation of beach mice to these locations. The Service's experience with other beach mice indicates that, with planning, beach mouse conservation and military activities are compatible.

The Federal Emergency Management Agency (FEMA) provides flood insurance for completed structures through the National Flood Insurance Program. Section 7 of the Act normally would require FEMA to consider conference or consultation with the Service where the agency provides flood insurance to private landowners with structures located in occupied habitat. In this case, private property occupied by the beach mouse within the St. Joseph Peninsula is also located within a CBRS unit and subject to the CBRA prohibitions against the acquisition of new federally-funded coastal flood insurance for new construction or substantial improvements (see factor D under ''Summary of Factors Affecting the Species''). The Service, therefore, believes the proposed listing will have no additional impact on the application of FEMA's flood insurance program.

U.S. Army Corps of Engineers involvement in the section 7 consultation process may result from the issuance of permits for the filling of wet interdunal swales subject to section 404 of the Clean Water Act (33 U.S.C. 1344 *et seq.*). Conference or consultation will be required should the Corps determine that such permit issuance may affect the St. Andrew beach mouse.

The Service may undertake internal consultations when carrying out recovery activities such as dune restoration and construction of pedestrian crossovers or when reviewing incidental take permit applications under section 10(a)(1)(B) of the Act.

The National Oceanic and Atmospheric Administration administers the Coastal Energy Impact Program (CEIP). CEIP is a Federal assistance program providing grant and loan assistance for use in planning studies, public works construction, land acquisition, and environmental loss mitigation projects, all associated with energy-related facility siting. Such a siting, however unlikely, within

occupied or potentially occupied habitat might result in some modification that minimizes or avoids impacts to the species. The great majority of section 7 consultations traditionally result either in no project changes or modifications rather than curtailment of the affected Federal activity.

Actions taken and in progress for the St. Andrew beach mouse include updated status surveys within a portion of the historic range, a population genetics analysis, and population viability modeling. Future actions include a translocation of some mice from the St. Joseph Peninsula to Crooked Island East through the cooperation and support of Tyndall Air Force Base. The Service plans to continue pursuing conservation actions it believes will be effective in measurably reducing the threats to the species' continued existence.

The Act and its implementing regulations set forth a series of general prohibitions and exceptions that apply to all endangered wildlife. The prohibitions, codified at 50 CFR 17.21, in part, make it illegal for any person subject to the jurisdiction of the United States to take (includes harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect; or to attempt any of these), import or export, ship in interstate commerce in the course of commercial activity, or sell or offer for sale in interstate or any foreign commerce any listed species. It is also illegal to possess, sell, deliver, carry, transport, or ship any such wildlife that has been taken illegally. Certain exceptions apply to agents of the Service and State conservation agencies.

Should this rule be finalized, the prohibitions of section 9 will not apply to St. Andrew Beach mice which were held in captivity or a controlled environment on the date of the final rulemaking, provided that such holding and any subsequent holding of such mice was not in the course of a commercial activity.

Permits may be issued to carry out otherwise prohibited activities involving endangered wildlife under certain circumstances. Regulations governing permits are codified at 50 CFR 17.22 and 17.23. Such permits are available for scientific purposes, to enhance the propagation or survival of the species, and/or for incidental take in the course of otherwise lawful activities.

It is the policy of the Service, published in the **Federal Register** on July 1, 1994 (59 FR 34272), to identify to the maximum extent practicable at the time a species is listed, those activities that would or would not constitute a violation of section 9 of the Act. The intent of this policy is to increase public awareness of the effect of this listing on proposed and ongoing activities within the species' range. The Service believes that, based on the best available information, the following actions will not result in a violation of section 9:

(1) Beneficial activities whose implementation does not result in take of beach mice. Such activities include, but are not limited to, boardwalk construction on or over dunes, use of snow fencing and planting of local, native dune vegetation to accelerate dune restoration, and dune reconstruction using beach quality sand.

(2) Normal residential activities on unoccupied habitat that would not result in take of beach mice, such as, landscape maintenance, private development and dune access by vehicles and pedestrians.

(3) Activities authorized, funded, or carried out by a Federal agency when the action is conducted in accordance with section 7 of the Act.

Potential activities involving the St. Andrew beach mouse that the Service believes will likely be considered a violation of section 9 include, but are not limited to, the following:

(1) Take of St. Andrew beach mouse without a permit.

(2) Possession, sale, delivery, carrying, transportation, or shipping of illegally taken St. Andrew beach mice.

(3) Destruction or alteration of occupied habitat that results in the death of or injury to the St. Andrew beach mouse through the significant impairment of essential behaviors including breeding, feeding, or sheltering.

Questions regarding whether specific activities will constitute a violation of section 9 or to obtain approved guidelines for actions within beach mouse habitat, contact the Field Supervisor of the Service's Panama City Field Office, 1612 June Avenue, Panama City, Florida 32405–3721 (telephone 850/769–0552). Requests for copies of the regulations concerning listed animals and inquiries regarding prohibitions and permits may be addressed to the U.S. Fish and Wildlife Service, Ecological Services, Permit Coordinator, 1875 Century Boulevard, Suite 200, Atlanta, Georgia 30345 (telephone 404/679–7110; facsimile 404/679–7081).

Public Comments Solicited

The Service intends that any final action resulting from this proposal will be as accurate and as effective as possible. Therefore, comments or suggestions from the public, other concerned governmental agencies, the scientific community, industry, or any other interested party concerning this proposed rule are hereby solicited. Comments particularly are sought concerning:

(1) Biological, commercial trade, or other relevant data concerning any threat (or lack thereof) to this species;

(2) The location of any additional populations of this species and the reasons why any habitat should or should not be determined to be critical habitat pursuant to section 4 of the Act;

(3) Additional information concerning the range, distribution, and population size of this species; and

(4) Current or planned activities in the subject area and their possible impacts on this species.

Final promulgation of the regulations on this species will take into consideration the comments and any additional information received by the Service, and such communications may lead to a final regulation that differs from this proposal.

The Act provides for one or more public hearings on this proposal, if requested. Requests must be received within 45 days of the date of publication of the proposal in the **Federal Register**. Such requests must be made in writing and be addressed to the Jacksonville Field Office (see **ADDRESSES** section).

National Environmental Policy Act

The Fish and Wildlife Service has determined that Environmental Assessments and Environmental Impact Statements, as defined under the authority of the National Environmental Policy Act of 1969, need not be prepared in connection with regulations adopted pursuant to section 4(a) of the Act. A notice outlining the Service's reasons for this determination was published in the **Federal Register** on October 25, 1983 (48 FR 49244).

Required Determinations

The Service has examined this regulation under the Paperwork Reduction Act of 1995 and found it to contain no information collection requirements.

References Cited

A complete list of all references cited herein, as well as others, is available upon request from the Jacksonville Field Office (see **ADDRESSES** section).

Author: The primary author of this document is John Milio (see **ADDRESSES** section).

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Reporting and

recordkeeping requirements, Transportation.

Proposed Regulation Promulgation

Accordingly, the Service hereby proposes to amend part 17, subchapter B of chapter I, title 50 of the Code of Federal Regulations, as set forth below:

PART 17—[AMENDED]

1. The authority citation for part 17 continues to read as follows:

Authority: 16 U.S.C. 1361–1407; 16 U.S.C. 1531–1544; 16 U.S.C. 4201–4245; Pub. L. 99–625, 100 Stat. 3500, unless otherwise noted.

2. Section 17.11(h) is amended by adding the following, in alphabetical order under MAMMALS, to the List of Endangered and Threatened Wildlife to read as follows:

§ 17.11 Endangered and threatened wildlife.

* * * * *

(h) * * *

Species		Historic range	Vertebrate population where endangered or threatened	Status	When listed	Critical habitat	Special rules
Common name	Scientific name						
Mammals							
*	*	*	*	*	*	*	
Mouse, St. Andrew beach.	Peromyscus polionotus peninsularis.	U.S.A.(FL)	Entire	E	.....	NA	NA
*	*	*	*	*	*	*	

Dated: October 2, 1997.

Jamie Rappaport Clark,

Director, Fish and Wildlife Service.

[FR Doc. 97–27549 Filed 10–16–97; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Parts 285, 630, 644, and 678

[I.D. 100897B]

Atlantic Highly Migratory Species; Scoping Meetings

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Scoping meetings; request for comments.

SUMMARY: NMFS will hold 21 scoping meetings to receive comments from fishery participants and other members of the public on Atlantic tunas, Atlantic swordfish, Atlantic shark, and Atlantic billfish fisheries. A scoping document of issues and options for Highly Migratory Species (HMS) fishery management is available for public comment (see **ADDRESSES**). The purpose of this announcement is to notify the public of meetings and provide for public participation in the management process.

DATES: Meetings will be held October 27 through November 17, 1997. See **SUPPLEMENTARY INFORMATION** for specific dates and times. Written comments on the issues must be received on or before December 1, 1997.

ADDRESSES: See **SUPPLEMENTARY INFORMATION** for meeting locations.

Written comments should be sent to Rebecca J. Lent, Chief, Highly Migratory Species Division, National Marine Fisheries Service, 1315 East-West Highway, Silver Spring, MD 20910. Clearly mark the outside of the envelope ''Scoping Comments.'' Copies of the scoping document can be requested by telephone: 301–713–2347 or fax: 301–713–1917.

FOR FURTHER INFORMATION CONTACT: Liz Lauck or Jill Stevenson, telephone: 301-713-2347.

SUPPLEMENTARY INFORMATION: NMFS is considering future management measures for Atlantic tunas, Atlantic swordfish, Atlantic shark, and Atlantic billfish fisheries to be included in a comprehensive Fishery Management Plan (FMP) for Atlantic tunas, swordfish and sharks, and an amendment to the Billfish FMP. Options for management may include long-term rebuilding programs, reallocation of quotas, recreational bag limits, commercial trip limits, minimum size restrictions, time/area closures, regional quotas, consistency between state and Federal regulations, gear restrictions, limited access, essential fish habitat, and permitting and reporting requirements.

Consistent with the new requirements of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act), NMFS established an HMS Advisory Panel (AP) and a billfish AP to assist in developing and amending FMPs for HMS species. In the case of any species identified as overfished, the APs would also assist in developing rebuilding programs.

The scoping meetings are intended to gather public input on a broad range of options to be considered in addressing HMS issues. The scoping document was developed with input from the APs and outlines major issues and options under consideration. NMFS is seeking public input on these and other issues and options for HMS fisheries.

As part of the FMP development process, NMFS intends to prepare Environmental Impact Statement (EIS) documents due to the potentially significant impact of upcoming regulations on the human environment, and because changes have occurred in the fisheries since the last EISs were prepared (62 FR 45614, August 28, 1997). Participants in the fishery, including processors, may be required to operate under alternative management measures that may redistribute fishing effort and/or mortality in order to facilitate recovery of HMS. The EIS documents will address the impacts of potential future management options on the natural and human environment for the Atlantic tuna, Atlantic swordfish, Atlantic shark, and Atlantic billfish fisheries.

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Liz Lauck at least 5 days before the meeting date (see **FOR FURTHER INFORMATION CONTACT**). Written comments on the issues and options for future management of HMS fisheries are also welcome.

Meeting Locations

The meeting schedule is as follows:

Monday, Oct 27, 1997, 7–10 p.m.

1. Holiday Inn, 290 State Highway 37 East, Toms River, NJ 08753, (908) 244–4000;

Monday, Oct 27, 1997, 6:30–9:30 p.m.

2. SC Dept. of Natural Resources, Marine Research Institute Auditorium, 217 Fort Johnson Road, Charleston, SC 29412, (803) 762–5037;

Tuesday, October 28, 1997, 7–10 p.m.

3. City Hall, 3rd Street and Baltimore Ave., Ocean City, MD 21842, (410) 289–8221;

4. Comfort Inn I–95, 5308 New Jessup Hwy., Brunswick, GA 31523, (912) 264–7268;

5. The San Luis, 5222 Sea Wall Blvd., Galveston, TX 77551, (409) 744–1500;

6. Holiday Inn (site of Mid-Atlantic Fishery Management Council meeting); 3900 Atlantic Ave., Virginia Beach, VA 23451, (757) 428–1711;

Wednesday, October 29, 1997, 7–10 p.m.

7. Holiday Inn, 1300 North Atlantic Ave., Cocoa Beach, FL 32931, (407) 783–2271;

8. NC Aquarium Auditorium, Airport Road, Manteo, NC 27954, (919) 473–3494;

9. The Hampton Inn, 32988 Perdido Beach Blvd., Orange Beach, AL 36561, (334) 974–1598;

Thursday October 30, 1997, 7–10 p.m.

10. Riverhead Town Hall, 200 Howell Ave. (corner E. Main), Riverhead, NY 11901, (516) 727–3200;

Monday, November 3, 1997, 7–10 p.m.

11. Holiday Inn (site of U.S. ICCAT Advisory Committee meeting), Georgia Ave., Silver Spring, MD 20910, (301) 589–0800;

Tuesday, November 4, 1997, 4–7 p.m.

12. Holiday Inn Beachside, Marquesas Room, 3841 N. Roosevelt Blvd., Key West, FL 33040, (305) 294–2571;

Tuesday, November 4, 1997, 7–10 p.m.

13. Holiday Inn By the Bay (site of New England Fishery Management Council meeting), 88 Spring St., Portland, ME 04101, (207) 775–2311;

Wednesday, November 5, 1997, 7–10 p.m.

14. Sheraton Biscayne Bay Hotel, Washington Room, 495 Brickell Ave., Miami, FL 33131, (305) 373–6000;

Thursday, November 6, 1997, 7–10 p.m.

15. Game Fishing Club of the Virgin Islands (above Frigate Restaurant), Red Hook, St. Thomas, U.S.V.I. 00802, (809) 775–9144;

16. Corliss Auditorium, Watkins Building, Graduate School of Oceanography, University of Rhode Island, 215 South Ferry Road, Narragansett, RI 02882, (401) 874–6222;

Friday, November 7, 1997, 10:00 a.m.–1:00 p.m.

17. International WorkBoat Show, Ernest N. Morial Convention Center - Room 16, New Orleans, LA 70898,(207) 842–5693;

Friday, November 7, 1997, 2–5 p.m.

18. NMFS, Northeast Regional Office, 1 Blackburn Drive,

Gloucester, MA 01930, (508) 281–9260;

19. Club Nautico, 482 Fernandez Juncos Ave., Old San Juan, PR 00905, (787) 722–0177;

Monday, November 10, 1997, 7–9 p.m.

20. Holiday Inn Long Boat Key (site of Gulf of Mexico Fishery Management Council meeting), 4949 Gulf of Mexico Drive, Long Boat Key, FL 34228, (941) 383–3771;

Monday, November 17, 1997, 7–10 p.m.

21. Duke University Marine Laboratory (site of South Atlantic Fishery Management Council meeting), 135 Duke Marine Lab Road, Beaufort, NC 28546, (919) 504–7504.

Additional meetings may be announced at a later date in the **Federal Register**.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: October 10, 1997.

Rebecca Lent,

Acting Director, Office of Sustainable Fisheries,

National Marine Fisheries Service.

[FR Doc. 97–27519 Filed 10–10–97; 4:23 pm]

BILLING CODE 3510–22–F

Notices

Federal Register

Vol. 62, No. 201

Friday, October 17, 1997

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Forest Service

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

Clancy-Unionville Vegetative Treatment/Travel Management Plan EIS; Helena National Forest, BLM Headwaters Resource Area, Lewis & Clark and Jefferson Counties, Montana

AGENCIES: Forest Service, USDA and Bureau of Land Management, USDI.

ACTION: Notice; intent to prepare Environmental Impact Statement and BLM Resource Management Plan (RMP) Amendment.

SUMMARY: The USDA, Forest Service and USDI, Bureau of Land Management are gathering information and preparing an Environmental Impact Statement (EIS) for a planning effort involving vegetative treatments and motorize travel management actions. This EIS will analyze the impacts of utilizing prescribed fire on grassland vegetation types and a combination of prescribed fire and tree removal within the forested vegetation. It will also evaluate the effects of alternative strategies for managing motorized travel uses throughout the affected area. Alternative travel management actions will address spatial, temporal and vehicle type allocations. Travel planning will also guide the long-term management of new roads needed to access the vegetation treatment areas. The project area is located immediately south of Helena, Montana, and totals 40,000 acres of public lands (including 5,000 acres of BLM lands).

The Forest Service and Bureau of Land Management propose to treat approximately 5750 acres of grassland and forested vegetation through prescribed burning and tree removal. On the National Forest, approximately 2800 acres would be treated with prescribed burning and 2200 acres of timber would be harvested. On the Bureau of Land Management lands approximately 750 acres would be harvested of which 250 acres would be treated further with prescribed burning.

Timber would be sold and removed using commercial thinning, selection, shelterwood, seedtree and clearcut harvest systems. Approximately 17.4 miles of new temporary road construction is needed to access treatment areas. Following treatment all but 1 mile of the temporary roads would be recontoured and physically closed. New road construction would occur in the Grizzly Gulch, Go Devil Creek, Whiteman Gulch, Little Buffalo Gulch, Jackson Creek, Lump Gulch and Quartz Creek vicinities.

The travel management proposal is to establish a ''Restricted Area'' designation for the entire area that would limit public motorized travel to designated routes. The use of some roads and trails would also be restricted to specific seasons and/or certain vehicle classes. Snowmobile users would be able to travel off routes in some portions of the area.

The proposal is designed to help achieve the goals and objectives of the 1986 Helena National Forest Plan and move selected areas towards the desired conditions identified from the Forest Plan. These needs are supported by the findings of the Divide Landscape Analysis (September 1996). This proposal would fulfill the vegetative management direction of the BLM Headwaters RMP and create some changes regarding travel management direction, ultimately requiring an amendment.

More specifically, the proposal has the following purpose:

- to create a more diverse forest with a wide variety of trees of varying ages, species and sizes.
- to minimize the threat of large scale, catastrophic wildfire by reducing the amount of forest vegetation (trees, shrubs and grasses) and litter on the forest floor. Vegetation treatments would be done in concert with the existing qualities of the urban/rural setting, while protecting the area's scenic and recreational amenities.
- to insure a variety of different plant and animal habitats which would meet the needs of the area's plant and animal species.
- to manage the area with designated roads and trails that serve the needs of a wide variety of public users, both motorized and non-motorized, while still protecting other resource values of the landscape.
- to produce an array of forest wood products (i.e. saw timber, post and pole material, firewood, Christmas trees) while still maintaining a sustainable forest.
- to improve water quality through sediment reduction measures and an up-dated travel management plan.

DATE: Comments concerning the scope of the analysis should be received in writing on or before November 17, 1997.

The draft EIS is scheduled for public release and comment in the spring of 1998.

ADDRESSES: The responsible officials are Tom Clifford, Forest Supervisor, Helena National Forest, Supervisor's Office, 2880 Skyway Drive, Helena, MT. 59601. Phone: (406) 449–5201, and James R. Owings, Butte District Manager, Bureau of Land Management, 106 N. Parkmont, Butte, MT. 59701, Phone (406) 494–5059.

FOR FURTHER INFORMATION CONTACT: Denis A. Hart, Helena District Ranger, Helena Ranger District, 2001 Poplar Helena, MT. 59601. Phone: (406) 449–5490; or Merle Good, Headwaters Resource Area Manager, P.O. Box 3388, Butte, MT. 59702. Phone: (406) 494–5059; or Fan Mainwaring, Interdisciplinary Team Leader, Helena Ranger District, 2001 Poplar, Helena, MT. 59601.

SUPPLEMENTARY INFORMATION: The prescribed burning, timber harvest, and temporary road construction would occur on National Forest and Bureau of Land Management lands in portions of Grizzly Gulch, Go Devil Creek, Whiteman Gulch, Little Buffalo Creek, Jackson Creek, Lump Gulch and Quartz Creek drainages of the Helena Ranger District of the Helena National Forest and Headwaters Resource Area of the Bureau of Land Management. Included in the area being analyzed is all or portions of T.10N., R.4W., Sections 34–35; T.9N., R.4W., Sections 1–5, 8–12, 20–23, 26–29; T9N., R3W., Sections 29–33; T8N., R3W., Sections 12–14, 25–27, 35–36; T8N., R4W., Sections 7–8, 17–20, 29–30, Montana Principle Meridian.

The areas of proposed tree removal and prescribed burning are within

Management Areas T–1, T–4, T–5, L–1, R–1, W–1 and M–1 described in the Helena Forest Plan. The Forest Plan direction states that:

—T–1 Lands available and suitable for timber production. Although these areas consist primarily of suitable forest lands, there are inclusions on non-forest and non-productive forest lands.

—T–4 Productive timberland within sensitive viewing area of many major travel routes, use areas and water bodies. Most of the area is suitable forest land, but there may be inclusions of non-forest or non-productive forest land.

—T–5 Suitable timberlands interspersed with natural openings, generally with existing livestock allotments.

—L–1 Generally nonforested forage producing areas where forage production is optimized and timber harvest and prescribed fire may be used as tools for this purpose, but not for timber management sake.

—R–1 These management areas consist of large blocks—greater than 3,000 acres—of undeveloped land suited for dispersed recreation. These areas provide opportunities for semi-primitive, non-motorized recreation and are characterized predominantly by natural or natural appearing environment where there is a high probability of isolation from man's activities.

—W–1 This management area consists of a variety of wildlife habitat ranging from important big game summer range to big game winter range.

—M–1 Non-forest and forested land where timber management and range or wildlife habitat improvements are currently uneconomical or environmentally infeasible.

The affected area of this EIS includes portions of Management Units (MUs) 8, 23 and 24 as described in the BLM Headwaters RMP of 1984. These MUs were identified as having high forest land values with a high priority for management. This vegetative treatment analysis will meet the RMP directive to complete a Compartment Management Plan in this area. The RMP designated MUs 8 and 24 as open to motorized travel and available for permitted motorized event consideration. MU 23 is classified as restricted to motorized travel and closed to motorized events. The travel management proposal complies with the RMP direction for MU 23 and is inconsistent with the direction for MUs 8 and 24. Therefore, Plan Amendment procedures will be followed in this EIS planning effort.

The decisions to be made, based on this environmental analysis, are:

1. Whether or not to treat the forested and nonforested vegetation at this time, and if so, what areas to treat, and what treatment methods would be employed.

2. What roads, trails, and areas need to be closed or restricted to ensure resource protection and what roads, trails and areas should remain open for motorized users.

If it is decided to implement the proposal, activities may begin as early as 1998 and take up to 3 years to implement.

This EIS will tier to the Helena Forest Plan Final EIS of April 1986 and the BLM Headwaters RMP of 1984 that provide program goals, objectives and standards and guidelines for conducting management activites in this area. All activities associated with the proposal will be designed to maintain or enhance the resource objectives identified in the two plans. The Forest Service will also strive to meet the objectives further refined in the Divide Landscape Analysis.

The Forest Service and the Bureau of Land Management are seeking information and comments from Federal, State, local agencies and others organizations or individuals who may be interested in or affected by the proposed action. The Forest Service and the Bureau of Land Management invite written comments and suggestions on the issues for the proposal and the area being analyzed. Information received will be used in preparation of the Draft EIS. Preparation of the EIS will include the following steps:

1. Identification of potential issues.

2. Identification of issues to be analyzed in depth.

3. Elimination of insignificant issues or those that have been covered by a relevant previous environmental analysis.

4. Identification of additional reasonable alternatives.

5. Identification of potential environmental effects of the alternatives.

Prescribed harvest treatments in this proposal include: a) unevenaged management techniques such as individual tree selection and group selection; b) intermediate treatments such as commercial thinning; and c) regeneration treatments include seedtree, shelterwood, and clearout harvest methods. Alternatives to this proposal will include the ''no action'' alternative, in which none of the proposed treatments would be implemented. Other alternatives will examine variations in the location, amount and method of vegetative management.

The preliminary issues identified are:

1. The effects of the vegetative treatments on existing noxious weed populations.

2. The effects of the vegetative treatments and temporary road construction on wildlife resources.

3. The effects of the vegetative treatments on existing recreation use.

4. The effectiveness of the vegetative treatment upon forest health and forest fuel accumulations.

5. The effects on threatened, endangered and sensitive plant and animal species.

6. The effects on motorized and non-motorized recreation use.

7. The economic trade-offs of implementing this proposal.

8. The effects on cultural resources within the project area.

9. The effects upon public safety and adjacent private lands from log hauling and prescribed burning.

The Forest Service and Bureau of Land Management will analyze and disclose in the DEIS and FEIS the environmental effects of the proposed action and a reasonable range of alternatives. The DEIS and FEIS will disclose the direct, indirect and cumulative environmental effects of each alternative and its associated site specific mitigation measures.

Public participation is especially important at several points of the analysis. Interested parties may visit with the Forest Service and Bureau of Land Management officials at any time during the analysis. However, two periods of time are specifically identified for the receipt of comments. The first comment period is during the scoping process when the public is invited to give written comments to the Forest Service and Bureau of Land management. This period extends for 30 days from the date of publication of this notice, in the **Federal Register**. The second review period is during the 45 day review of the DEIS in and when the public is invited to comment on the DEIS.

The DEIS is expected to be filed with the Environmental Protection Agency (EPA) and available for public review in March 1998. At that time, the EPA will publish a notice of availability of the DEIS in the **Federal Register**.

The comment period on the DEIS will be 45 days from the date the notice of availability is published in the **Federal Register.**

At this early stage in the scoping process, the Forest Service and the Bureau of Land Management believe it is important to give reviewers notice of several court rulings related to public participation in the environmental review process. First, reviews of DEIS

must structure their participation in the environmental review of the proposal so that it is meaningful and alerts an agency to the reviewer's position and contentions. *Vermont Yankee Nuclear Power Corp.* v. *NRDC,* 435 U.S. 519, 553 (1978). Secondly, environmental objections that could be raised at the draft environmental impact statement stage, but that are not raised until after completion of the FEIS may be waived or dismissed by the courts. *City of Angoon* v. *Hodel,* 803 F. 2d 1016, 1022 (9th Cir. 1986) and Wisconsin Heritages, Inc. v. Harris, 490 F. Supp. 1338 (E.D. Wis. 1980). Because of these court rulings, it is very important that those interested in this proposed action participate by the close of the 45-day comment period so that substantive comments and objects are made available to the Forest Service and Bureau of Land Management at a time when they can meaningfully consider them and respond to them in the FEIS.

To assist the Forest Service and Bureau of Land Management in identifying and considering issues and concerns on the proposed action, comments on the DEIS should be as specific as possible. It is also helpful if comments refer to specific pages or chapters of the draft statement. Comments may also address the adequacy of the DEIS or the merits of the alternatives formulated and discussed in the statement. (Reviewers may wish to refer to the Council on Environmental Quality Regulations for implementing the procedural provisions of the National Environmental Policy Act at 40 CFR 1503.3 in addressing these points.)

After the comment period ends on the DEIS, the comments will be analyzed and considered by the Forest Service and Bureau of Land Management in preparing the FEIS. The FEIS is expected to be filed in July 1998.

Dated: October 6, 1997.

Tom Clifford,

Forest Supervisor, Helena National Forest.

Dated: September 29, 1997.

James R. Owings,

Butte District Manager, Bureau of Land management.

[FR Doc. 97–27542 Filed 10–16–97; 8:45 am]

BILLING CODE 3410–11–M

DEPARTMENT OF AGRICULTURE

Forest Service

Squirrel Meadows-Grand Targhee Resort Land Exchange; Targhee National Forest, Teton County, Wyoming

AGENCY: Forest Service, USDA.

ACTION: Notice of intent to prepare environmental impact statement.

SUMMARY: The U.S. Department of Agriculture, Forest Service will prepare an environmental impact statement (EIS) to document the analysis and disclose the environmental impacts of a proposed land exchange with Booth Creek, Inc., dba Grand Targhee Resort.

In this proposed exchange the Targhee National Forest would trade parcels of National Forest System Lands totaling about 265 acres to Booth Creek, Inc., for a private parcel totaling approximately 330 acres. The National Forest System lands to be conveyed are located at the base of the Grand Targhee Resort, 7 miles east of Alta, Wyoming. The lands to be acquired are located at Squirrel Meadows, 26 miles east of Ashton, Idaho.

Values of the parcels will be appraised following a process stipulated for Federal land adjustments. In order for the exchange to take place, the appraised values of the lands must be equal. Differences in appraised values may be made up by reducing the acreage of National Forest System lands offered for exchange, or by including a cash payment. The cash value may not exceed 25 percent of the appraised value of the Federal lands to be conveyed.

DATES: Written comments concerning the scope of the analysis described in this notice should be received on or before December 1, 1997.

ADDRESSES: Send written comments to Teton Basin Ranger District, Attn: Jack Haddox, PO Box 777, Driggs, ID 83422. The responsible official for this decision is Robert W. Ross, Jr., Director, Recreation and Lands, USDA Forest Service, Intermountain Region, 324 25th Street, Ogden, UT 84401.

FOR FURTHER INFORMATION CONTACT: Questions concerning the proposed action and EIS should be directed to Patty Bates, Teton Basin District Ranger, Targhee National Forest, phone: (208) 354–2312.

SUPPLEMENTARY INFORMATION: The Targhee National Forest is proposing to exchange up to 265 acres of National Forest System lands within the Grand Targhee Resort permit area for 330 acres of private land at Squirrel Meadows. The final acreage will be decided through an appraisal process pursuant to the Uniform Federal Appraisal Standards for land adjustments. Values must be equal in order for the exchange to proceed. If it becomes necessary to equalize values the National Forest System acreage may be reduced from the proposed 265 acres. In the event the values cannot be equalized by the adjustment a cash equalization payment of up to 25 percent of the appraised value of the Federal lands may be made by either party.

The decision to be made is whether to proceed with the exchange as proposed; modify the exchange; or withdraw from the exchange. Public scoping will be completed through letters, news releases and public meetings. Dates have not yet been set.

Preliminary issues identified are:

(1) Impacts from potential development of the exchanged lands at Grand Targhee on the base area and in Teton Valley, Idaho.

(2) Impacts on wildlife in the area of Grand Targhee from potential development and increased use of the area in general.

(3) Impacts on the Jedediah Smith Wilderness from the potential increased use and development of the grand Targhee area.

(4) Creation of a private inholding within the boundary of the Targhee National Forest.

(5) The effects on grizzly bears (listed as threatened under the Endangered Species Act) and other threatened, endangered and sensitive species from the potential development of the exchanged lands and potential development of the lands if they are not exchanged.

Other issues may be identified during the scoping period. Written suggestions and comments are invited on the issues related to the proposal and the area being analyzed. Information received will be used in the preparation of the Draft EIS and Final EIS. For most effective use, comments should be submitted to the Forest Service within 45 days from the date of publication of this notice in the Federal Register.

The Forest Service is the lead agency. The Forest Service estimates the draft EIS will be filed in May, 1998, and the final EIS will be filed in December, 1998.

The comment period on the draft environmental impact statement will be 45 days from the date the Environmental Protection Agency's notice of availability appears in the **Federal Register.**

The Forest Service believes, at this early stage, it is important to give

reviewers notice of several court rulings related to public participation in the environmental review process. First, reviewers of draft environmental impact statements must structure their participation in the environmental review of the proposal so that it is meaningful and alerts an agency to the reviewer's position and contentions. *Vermont Yankee Nuclear Power Corp.* v. *NRDC,* 435 U.S. 519, 533 (1978). Also, environmental objections that could be revised at the draft environmental impact statement stage but that are not raised until after completion of the final environmental impact statement may be waived or dismissed by the courts. *City of Angoon* v. *Hodel,* 803 F.2d 1016, 1022 (9th Circ 1986) and *Wisconsin Heritages, Inc.* v. *Harris,* 490 F. Supp. 1334, 1338 (E.D.) Wis. 1980. Because of these court rulings, it is very important that those interested in this proposed action participate by the close of the 45-day comment period so that substantive comments and objections are made available to the Forest Service at a time when it can meaningfully consider them and respond to them in the final environmental impact statement.

To assist the Forest Service in identifying and considering issues and concerns on the proposed action, comments on the draft environmental impact statement should be as specific as possible. It is also helpful if comments refer to specific pages or chapters of the draft environmental impact statement. Comments may also address the adequacy of the draft environmental impact statement or the merits of the alternatives formulated and discussed in the statement. Reviewers may wish to refer to the Council on Environmental Quality Regulations for implementing the procedural provisions of the National Environmental Policy Act at 40 CFR 1503.3 in addressing these points.

Comments received in response to this solicitation, including names and addresses of those who comment, will be considered part of the public record on this proposed action and will be available for public inspection. Comments submitted anonymously will be accepted and considered; however, those who submit anonymous comments will not have standing to appeal the subsequent decision under 36 CFR Parts 215 or 217. Additionally, pursuant to 7 CFR 1.27(d), any person may request the agency to withhold a submission from the public record by showing how the Freedom of Information Act (FOIA) permits such confidentiality. Persons requesting such confidentiality should be aware that, under the FOIA, confidentiality may be granted in only very limited circumstances, such as to protect trade secrets. The Forest Service will inform the requester of the agency's decision regarding the request for confidentiality, and where the request is denied, the agency will return the submission and notify the requester that the comments may be resubmitted with or without name and address within 15 days.

Dated: October 9, 1997.

Jack A. Blackwell,

Deputy Regional Forester, Intermountain Region, USDA Forest Service.

[FR Doc. 97–27569 Filed 10–16–97; 8:45 am]

BILLING CODE 3410–11–M

DEPARTMENT OF AGRICULTURE

Forest Service

Use of Certified Forage To Prevent the Spread of Noxious Weeds on National Forest System Lands in Montana

AGENCY: Forest Service, USDA.

ACTION: Notice: adoption of final policy.

SUMMARY: The Regional Forester for the Northern Region of the Forest Service has adopted a final policy which prohibits the use of hay, grain, straw, cubes or pelletized feed on National Forest System lands in Montana unless it is certified as free of noxious weeds or noxious weed seeds. This requirement will affect such users as recreationists using pack and saddle stock, ranchers operating under Forest Service grazing permits, outfitters and guides operating under Forest Service permits, and contractors who use straw or hay for reseeding or erosion control purposes on National Forest System-administered lands in Montana. This proposal has been developed in coordination with the State of Montana and Bureau of Land Management Montana State Office, which is publishing a similar decision in a separate notice in this same part of today's **Federal Register**. The intended effect is to coordinate prevention of the spread of undesirable weeds on federal lands in Montana.

DATES: Effective immediately.

FOR FURTHER INFORMATION CONTACT: James Olivarez, Forest and Rangeland Staff, Northern Region, Forest Service, (406) 329–3621.

SUPPLEMENTARY INFORMATION: Pursuant to 36 CFR 261.50, the Regional Forester is issuing orders to close or restrict uses on National Forest System lands. As adopted, this requirement to close National Forest System lands to users who do not use a certified weed-free forage or similar products results in a standard closure order applicable to all National Forest System lands in Montana. The Northern Regional Forester has been implementing a similar policy on a forest-by-forest basis in Montana since 1989. The Montana State Office of the Bureau of Land Management (BLM) is adopting a similar standard requirement for all public lands under its jurisdiction. The BLM decision appears in a separate notice in this part of today's **Federal Register.**

Response to Public Comments

There was one written comment received. It was in support of this policy implementation via a closure order.

The text of the Special Closure Order shall be published in newspapers across the State of Montana, as well as direct notification by mail of interested and effected groups and individuals.

Dated; October 9, 1997.

Hal Salwasser,

Regional Forester.

[FR Doc. 97–27574 Filed 10–16–97; 8:45 am]

BILLING CODE 3410–11–M

U.S. ARCTIC RESEARCH COMMISSION

Meeting

Notice is hereby given that the U.S. Arctic Research Commission will hold its 49th Meeting in Arlington, VA on November 3 and 4, 1997. On Monday, November 3, the Commission will conduct an invitation only program review. This review will concentrate on three topics:

(1) Global Change in the Arctic.

(2) Arctic Native Environmental Health Issues.

(3) Petroleum Exploitation in the Arctic.

On Tuesday, November 4 the Commission will hold a Business Session. Agenda items include:

(1) Call to order and approval of the Agenda.

(2) Approval of the minutes of the 48th Meeting.

(3) Reports of Congressional Liaisons.

(4) Agency Reports.

Any person planning to attend the Tuesday meeting who requires special accessibility features and/or auxiliary aids, such as sign language interpreters must inform the Commission in advance of those needs.

Contact Person for More Information: Dr. Garrett W. Brass, Executive Director,

Arctic Research Commission, 703–525–0111 or TDD 703–306–0090.

Garrett W. Brass,

Executive Director.

[FR Doc. 97–27617 Filed 10–16–97; 8:45 am]

BILLING CODE 7555–01–M

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Proposed Additions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Proposed additions to Procurement List.

SUMMARY: The Committee has received proposals to add to the Procurement List commodities and services to be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities.

COMMENTS MUST BE RECEIVED ON OR BEFORE: November 17, 1997.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, Crystal Square 3, Suite 403, 1735 Jefferson Davis Highway, Arlington, Virginia 22202–3461.

FOR FURTHER INFORMATION CONTACT: Beverly Milkman (703) 603–7740.

SUPPLEMENTARY INFORMATION: This notice is published pursuant to 41 U.S.C. 47(a)(2) and 41 CFR 51–2.3. Its purpose is to provide interested persons an opportunity to submit comments on the possible impact of the proposed actions.

If the Committee approves the proposed additions, all entities of the Federal Government (except as otherwise indicated) will be required to procure the commodities and services listed below from nonprofit agencies employing persons who are blind or have other severe disabilities. I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will furnish the commodities and services to the Government.

2. The action does not appear to have a severe economic impact on current contractors for the commodities and services.

3. The action will result in authorizing small entities to furnish the commodities and services to the Government.

4. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46–48c) in connection with the commodities and services proposed for addition to the Procurement List. Comments on this certification are invited.

Commenters should identify the statement(s) underlying the certification on which they are providing additional information.

The following commodities and services have been proposed for addition to Procurement List for production by the nonprofit agencies listed:

Commodities

Fly Tent, Nylon, Polyurethane Coated
8340–00–102–6370
8340–01–185–5512
NPA: Alabama Industries for the Blind, Talladega, Alabama

Character Lunch Bags
M.R. 402
NPA: Winston-Salem Industries for the Blind, Winston-Salem, North Carolina

Services

Administrative Services
General Services Administration, PBS
Sacramento Field Office
Sacramento, California
NPA: Goodwill Labor Power, Inc., Sacramento, California

Operation of Customer Supply Center
Hickam Air Force Base, Hawaii
NPA: Makaala Inc., Honolulu, Hawaii

Beverly L. Milkman,

Executive Director.

[FR Doc. 97–27625 Filed 10–16–97; 8:45 am]

BILLING CODE 6353–01–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Addition and Deletions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Addition to and deletions from the Procurement List.

SUMMARY: This action adds to the Procurement List a service to be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities, and deletes from the Procurement List services previously furnished by such agencies.

EFFECTIVE DATE: November 17, 1997.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, Crystal Square 3, Suite 403, 1735 Jefferson Davis Highway, Arlington, Virginia 22202–3461.

FOR FURTHER INFORMATION CONTACT: Beverly Milkman (703) 603–7740.

SUPPLEMENTARY INFORMATION: On August 22 and 29, 1997, the Committee for Purchase From People Who Are Blind or Severely Disabled published notices (62 F.R. 44637 and 45792) of proposed addition to and deletions from the Procurement List.

Addition

After consideration of the material presented to it concerning capability of qualified nonprofit agencies to provide the service and impact of the addition on the current or most recent contractors, the Committee has determined that the service listed below is suitable for procurement by the Federal Government under 41 U.S.C. 46–48c and 41 CFR 51–2.4.

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will furnish the service to the Government.

2. The action will not have a severe economic impact on current contractors for the service.

3. The action will result in authorizing small entities to furnish the service to the Government.

4. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46–48c) in connection with the service proposed for addition to the Procurement List.

Accordingly, the following service is hereby added to the Procurement List:

Access Control
Fleet and Industrial Supply Center
Oakland, California

This action does not affect current contracts awarded prior to the effective date of this addition or options that may be exercised under those contracts.

Deletions

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or

other compliance requirements for small entities.

2. The action will not have a severe economic impact on future contractors for the services.

3. The action will result in authorizing small entities to furnish the services to the Government.

4. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46–48c) in connection with the services deleted from the Procurement List.

After consideration of the relevant matter presented, the Committee has determined that the services listed below are no longer suitable for procurement by the Federal Government under 41 U.S.C. 46–48c and 41 CFR 51–2.4.

Accordingly, the following services are hereby deleted from the Procurement List:

Administrative Services

Federal Supply Service
Tool Acquisition Division I
2611 Jefferson Davis Highway
Arlington, Virginia

Commissary Shelf Stocking
Naval Air Station
Alameda, California

Commissary Shelf Stocking
Naval Air Station
Long Beach, California

Commissary Shelf Stocking and Custodial
Naval Station
Treasure Island, California

Food Service

White Sands Missile Range
Consolidated Dining Facility
White Sands, New Mexico

Janitorial/Custodial
Social Security Administration
4377 Mission Street
San Franciso, California

Janitorial/Custodial
Weather Bureau Building
2400 M Street, NW
Washington, DC

Janitorial/Custodial
Naval Air Warfare Center
Aircraft Division
6000 E. 21st Street
Indianapolis, Indiana

Janitorial/Custodial
Nuclear Regulatory Commission Warehouse
5000–5010 Boiling Brook Parkway
Rockville, Maryland

Janitorial/Custodial
Federal Building
35 Ryerson Street
Brooklyn, New York

Janitorial/Custodial
U.S. Army Reserve Center
Huntingdon, Pennsylvania

Janitorial/Custodial
U.S. Army Reserve Center
Moore Hall
Salt Lake City, Utah

Photocopying
National Agricultural Library Building
Beltsville, Maryland

Repair and Maintenance of Electric Typewriters
General Services Administration
(including Onondaga County)
Syracuse, New York

Beverly L. Milkman,

Executive Director.

[FR Doc. 97–27626 Filed 10–16–97; 8:45 am]

BILLING CODE 6353–01–P

DEPARTMENT OF COMMERCE

Submission for OMB Review; Comment Request

DOC has submitted to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35). This collection has been submitted under the emergency Paperwork Reduction Act procedures.

Agency: Bureau of Export Administration.

Title: Reporting and Recordkeeping Requirements Under the Wassenaar Arrangement.

Agency Form Number: None.

OMB Approval Number: None.

Type of Request: New Collection—Emergency Review.

Burden: 851 Hours.

Number of Respondents: 2,275.

Avg. Hours per Response: Ranges between one and ten minutes depending on the requirement.

Needs and Uses: This collection of information is required as the result of a multilateral export control agreement called the Wassenaar Arrangement on Export Controls for Conventional Arms and Dual-use Goods and Technologies (Wassenaar Arrangement). The Wassenaar Arrangement contributes to regional and international security and stability by promoting transparency and greater responsibility in the transfers of conventional arms and dual-use goods and technologies, thus preventing destabilizing accumulations of such items.

Affected Public: Individuals, businesses or other for-profit and not-for-profit institutions.

Frequency: On occasion.

Respondent's Obligation: Mandatory.

OMB Desk Officer: Victoria Baecher-Wassmer or Pat Boyd, (202) 395–5871.

Copies of the above information collection proposal can be obtained by calling or writing Linda Engelmeier, Departmental Clearance Officer, (202) 482–3272, U.S. Department of Commerce, Room 5312, 14th and Constitution Avenue, NW, Washington DC 20230.

Written comments and recommendations for the proposed information collection should be sent to Pat Boyd or Victoria Baecher-Wassmer, OMB Desk Officer, Room 10202, New Executive Office Building, 725 17th Street, N.W., Washington, DC 20503. An emergency approval has been requested by Friday, October 17, 1997.

Dated: October 9, 1997.

Linda Engelmeier,

Departmental Forms Clearance Officer, Office of Management and Organization.

[FR Doc. 97–27524 Filed 10–16–97; 8:45 am]

BILLING CODE 3510–DT–P

DEPARTMENT OF COMMERCE

Submission for OMB Review; Comment Request

The Department of Commerce (DOC) has submitted to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Agency: National Oceanic and Atmospheric Administration (NOAA).

Title: Regulations Under the Marine Mammal Protection Act Governing the Small Take of Marine Mammals Incidental to Specified Activities.

Agency Form Number: None.

OMB Approval Number: 0648–0151.

Type of Request: Reinstatement of a previously approved collection.

Burden: 3,926.

Number of Respondents: 35.

Avg Hours Per Response: 60 hours (requests for regulations average 483 hours, applications for Letters of Authorization average 3 hours, applications for Incidental Harassment Authorizations average 200 hours, and reports range from 30–150 hours a response.

Needs and Uses: The harassment, injury or death of marine mammals is prohibited by the Marine Mammal Protection Act (MMPA), unless permitted, exempted, or otherwise authorized. Providing the taking (harassment, injury, mortality) is negligible, maritime activities that result in the incidental taking of marine

mammals need an authorization under the MMPA to avoid prosecution under the MMPA. The Act requires applicants to submit information justifying the authorization. The MMPA also requires monitoring and reporting on marine mammal interactions with the activity.

Affected Public: Federal Government, businesses or other for-profit organizations, not-for-profit institutions and state, local or tribal government.

Frequency: Annually, and 90 day reporting requirements.

Respondent's Obligation: Required to obtain or retain a benefit.

OMB Desk Officer: David Rostker, (202) 395–3897.

Copies of the above information collection proposal can be obtained by calling or writing Linda Engelmeier, DOC Forms Clearance Officer, (202) 482–3272, Department of Commerce, Room 5327, 14th and Constitution Avenue, N.W., Washington, D.C. 20230.

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to David Rostker, OMB Desk Officer, Room 10202, New Executive Office Building, 725 17th Street, N.W., Washington, D.C. 20503.

Dated: October 9, 1997.

Linda Engelmeier,

Departmental Forms Clearance Officer, Office of Management and Organization

[FR Doc. 97–27526 Filed 10–16–97; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

Submission for OMB Review; Comment Request

The Department of Commerce (DOC) has submitted to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Agency: National Oceanic and Atmospheric Administration (NOAA).

Title: Information for Share Transfer in Wreckfish Fishery.

Agency Form Number: None.

OMB Approval Number: 0648–0262.

Type of Request: Reinstatement of a previously approved collection.

Burden: 1 hour.

Avg. Hours Per Response: 15 minutes.

Number of Responses: 4.

Needs and Uses: The individual transferable quota system for the wreckfish fishery is based on percentage shares. The purpose of this collection is to provide information on the transfer of ownership of percentage shares.

Affected Public: Individuals, businesses or other for-profit organizations.

Frequency: On occasion.

Respondent's Obligation: Required to obtain or retain a benefit.

OMB Desk Officer: David Rostker, (202) 395–3897.

Copies of the above information collection proposal can be obtained by calling or writing Linda Engelmeier, DOC Forms Clearance Officer, (202) 482–3272, Department of Commerce, Room 5327, 14th and Constitution Avenue, N.W., Washington, D.C. 20230.

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication to David Rostker, OMB Desk Officer, Room 10202, New Executive Office Building, 725 17th Street, N.W., Washington, D.C. 20503.

Dated: October 10, 1997.

Linda Engelmeier,

Departmental Forms Clearance Officer, Office of Management and Organization.

[FR Doc. 97–27577 Filed 10–16–97; 8:45 am]

BILLING CODE: 3510–22–P

DEPARTMENT OF COMMERCE

Submission for OMB Review; Comment Request

The Department of Commerce (DOC) has submitted to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Agency: National Oceanic and Atmospheric Administration (NOAA).

Title: Foreign Fishing Regulations.

Agency Form Number: None.

OMB Approval Number: 0648–0075.

Type of Request: Reinstatement of a previously approved collection.

Burden: 330 hours.

Avg. Hours Per Response: 6 minutes.

Number of Respondents: 110 with multiple responses.

Needs and Uses: Foreign fishing activities can be authorized under the Magnuson-Stevens Fishery Conservation and Management Act. Collection of information from permitted foreign vessels is necessary for enforcement by allowing the monitoring of vessel activities and whereabouts in U.S. waters. Reports are also necessary for fishery management purposes to monitor the amount of fish caught or received by foreign vessels.

Affected Public: Businesses or other for-profit organizations.

Frequency: On occasion, weekly.

Respondent's Obligation: Mandatory.

OMB Desk Officer: David Rostker, (202) 395–3897.

Copies of the above information collection proposal can be obtained by calling or writing Linda Engelmeier, DOC Forms Clearance Officer, (202) 482–3272, Department of Commerce, Room 5327, 14th and Constitution Avenue, N.W., Washington, D.C. 20230.

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to David Rostker, OMB Desk Officer, Room 10202, New Executive Office Building, 725 17th Street, N.W., Washington, D.C. 20503.

Dated: October 10, 1997.

Linda Engelmeier,

Departmental Forms Clearance Officer, Office of Management and Organization.

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DEPARTMENT OF COMMERCE

International Trade Administration

[A–427–801, A–428–801, A–475–801, A–588–804, A–485–801, A–559–801, A–401–801, A–412–801]

Antifriction Bearings (Other Than Tapered Roller Bearings) and Parts Thereof From France, Germany, Italy, Japan, Romania, Singapore, Sweden and the United Kingdom; Final Results of Antidumping Duty Administrative Reviews

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Notice of final results of antidumping duty administrative reviews.

SUMMARY: On June 10, 1997, the Department of Commerce (the Department) published the preliminary results of administrative reviews of the antidumping duty orders on antifriction bearings (other than tapered roller bearings) and parts thereof from France, Germany, Italy, Japan, Romania, Singapore, Sweden, and the United Kingdom. The classes or kinds of merchandise covered by these orders are ball bearings and parts thereof, cylindrical roller bearings and parts thereof, and spherical plain bearings and parts thereof. The reviews cover 21 manufacturers/exporters. The period of review (POR) is May 1, 1995, through April 30, 1996.

Based on our analysis of the comments received, we have made changes, including corrections of certain

inadvertent programming and clerical errors, in the margin calculations. Therefore, the final results differ from the preliminary results. The final weighted-average dumping margins for the reviewed firms are listed below in the section entitled ''Final Results of the Reviews.''

EFFECTIVE DATE: October 17, 1997.

FOR FURTHER INFORMATION CONTACT: The appropriate case analyst, for the various respondent firms listed below, of Import Administration, International Trade Administration, U.S. Department of Commerce, Washington, DC 20230; telephone: (202) 482–4733.

France

Chip Hayes (SKF), Lyn Johnson (SNFA), Michael Panfeld (SNR), Robin Gray or Richard Rimlinger.

Germany

John Heires (Torrington Nadellager), J. David Dirstine (SKF), Suzanne Flood (INA), Michael Panfeld (NTN Kugellagerfabrik), Thomas Schauer (FAG), Robin Gray or Richard Rimlinger.

Italy

Chip Hayes (SKF), Mark Ross (FAG) or Richard Rimlinger.

Japan

J. David Dirstine (Koyo Seiko), Gregory Thompson (NTN), Kristie Strecker (NPBS), Thomas Schauer (NSK Ltd., Nachi-Fujikoshi Corp.) or Richard Rimlinger.

Romania

Kristie Strecker (Tehnoimportexport, S.A.) or Robin Gray.

Singapore

Lyn Johnson (NMB/Pelmec) or Richard Rimlinger.

Sweden

Mark Ross (SKF) or Richard Rimlinger.

United Kingdom

Hermes Pinilla (FAG, Barden, NSK/RHP) or Robin Gray.

SUPPLEMENTARY INFORMATION:

The Applicable Statute

Unless otherwise indicated, all citations to the Tariff Act of 1930, as amended (the Tariff Act), are references to the provisions effective January 1, 1995, the effective date of the amendments made to the Tariff Act by the Uruguay Round Agreements Act (URAA). In addition, unless otherwise indicated, all citations to the Department's regulations are to 19 CFR Part 353 (1997).

Background

On June 10, 1997, the Department of Commerce (the Department) published the preliminary results of administrative reviews of the antidumping duty orders on antifriction bearings (other than tapered roller bearings) and parts thereof (AFBs) from France, Germany, Italy, Japan, Romania, Singapore, Sweden, and the United Kingdom (62 FR 31566). The reviews cover 21 manufacturers/exporters. The period of review (the POR) is May 1, 1995, through April 30, 1996. We invited parties to comment on our preliminary results of review. At the request of certain interested parties, we held public hearings for General Issues on July 8, 1997, and for Japan-specific issues on July 15, 1997. The Department has conducted these administrative reviews in accordance with section 751 of the Tariff Act.

Scope of Reviews

The products covered by these reviews are AFBs and constitute the following classes or kinds of merchandise: Ball bearings and parts thereof (BBs), cylindrical roller bearings and parts thereof (CRBs), and spherical plain bearings and parts thereof (SPBs). For a detailed description of the products covered under these classes of kinds of merchandise, including a compilation of all pertinent scope determinations, *see* the ''Scope Appendix,'' which is appended to this notice of final results.

Use of Facts Available

For a discussion of our application of facts available, *see* the ''Facts Available'' section of the Issues Appendix.

Sales Below Cost in the Home Market

The Department disregarded home market (HM) sales below cost for the following firms and classes or kinds of merchandise for these final results of reviews:

Country	Company	Class or kind of merchandise
France	SKF	BBs
	SNR	BBs
Germany	NTN	BBs
	FAG	BBs, CRBs, SPBs
	INA	BBs, CRBs, SPBs
	SKF	BBs, CRBs, SPBs
Italy	FAG	BBs
	SKF	BBs
Japan	Koyo	BBs, CRBs
	Nachi	BBs, CRBs
	NSK	BBs, CRBs
	NTN	BBs, CRBs, SPBs
	NPBS	BBs
Singapore	NMB/Pelmec.	BBs
Sweden	SKF	BBs
United Kingdom	NSK–RHP.	BBs, CRBs
	Barden	BBs

Duty Absorption

We have determined that duty absorption has occurred with respect to the following firms and with respect to the following percentages of sales which these firms made through their U.S. affiliated parties:

Name of Firm	Class or kind	Percentage of U.S. affiliate's sales with dumping margins
France		
SKF	BBs	23.24
	SPBs	100.00
SNR	BBs	36.22
	CRBs	44.64
Germany		
FAG	BBs	54.57
	CRBs	40.14
	SPBs	21.10
INA	BBs	64.47
	CRBs	40.89
NTN	BBs	36.44
SKF	BBs	7.03
	CRBs	53.78
	SPBs	21.17
Italy		
FAG	BBs	20.43
SKF	BBs	8.15
Japan		
Koyo Seiko	BBs	49.49
	CRBs	86.02
Nachi	BBs	58.49
	CRBs	31.87
NPBS	BBs	55.46
NSK	BBs	24.23
	CRBs	36.19
NTN	BBs	37.50
	CRBs	19.26
	SPBs	73.03
Singapore		
NM Singapore/Pelmec Inc..	BBs	8.51
Sweden		
SKF	BBs	45.26
United Kingdom		
NSK/RHP	BBs	27.76
	CRBs	52.51
Barden	BBs	13.36

For a discussion of our determination with respect to this matter, *see* the ''Duty Absorption'' section of the Issues Appendix.

Changes Since the Preliminary Results

Based on our analysis of comments received, we have made certain corrections that changed our results. We have corrected certain programming and clerical errors in our preliminary results, where applicable. Any alleged programming or clerical errors with which we do not agree are discussed in the relevant sections of the Issues Appendix.

Analysis of Comments Received

All issues raised in the case and rebuttal briefs by parties to these concurrent administrative reviews of AFBs are addressed in the ''Issues Appendix'' which is appended to this notice of final results.

Final Results of Reviews

We determine that the following percentage weighted-average margins exist for the period May 1, 1995, through April 30, 1996:

Company	BBs	CRBs	SPBs
France			
SKF	5.38	(2)	42.79
SNFA	66.42	18.37	(3)
SNR	8.60	10.14	(2)
Germany			
FAG	12.40	19.49	10.32
INA	49.62	20.08	28.62
NTN	9.44	(2)	(2)
SKF	4.25	17.82	4.72
Torrington Nadellager	(3)	76.27	(3)
Italy			
FAG	1.76	(1)	.....
SKF	3.59	(3)	.....
Japan			
Koyo Seiko	14.20	15.38	(1)
NPBS	16.70	(2)	(2)
NSK	9.88	6.88	(2)
NTN	7.10	3.86	7.69
Nachi	12.89	3.15	(2)
Romania			
TIE	.20	.....	.....
Singapore			
NMB Singapore/ Pelmec Ind.	2.10	.....	.....
Sweden			
SKF	12.62	.....	.....
United Kingdom			
NSK–RHP	16.49	68.26	.....
Barden	4.00	(1)	.....

[1] No shipments or sales subject to this review. Rate is from the last relevant segment of the proceeding in which the firm had shipments/sales.

[2] No shipments or sales subject to this review. The firm has no individual rate from any segment of this proceeding.

[3] No review.

Assessment Rates

The Department shall determine, and the Customs Service shall assess, antidumping duties on all appropriate entries. Because sampling and other simplification methods prevent entry-by-entry assessments, we will calculate wherever possible an exporter/importer-specific assessment rate for each class or kind of AFBs.

1. Export Price Sales

With respect to export price (EP) sales for these final results, we divided the total dumping margins (calculated as the difference between normal value (NV) and EP) for each importer/customer by the total number of units sold to that importer/customer. We will direct Customs to assess the resulting per-unit dollar amount against each unit of merchandise in each of that importer's/customer's entries under the relevant order during the review period. Although this will result in assessing different percentage margins for individual entries, the total antidumping duties collected for each importer/customer under each order for the review period will be almost exactly equal to the total dumping margins.

2. Constructed Export Price Sales

For constructed export price (CEP) sales (sampled and non-sampled), we divided the total dumping margins for the reviewed sales by the total entered value of those reviewed sales for each importer/customer. We will direct Customs to assess the resulting percentage margin against the entered Customs values for the subject merchandise on each of that importer's/customer's entries under the relevant order during the review period. While the Department is aware that the entered value of sales during the POR is not necessarily equal to the entered value of entries during the POR, use of entered value of sales as the basis of the assessment rate permits the Department to collect a reasonable approximation of the antidumping duties which would have been determined if the Department had reviewed those sales of merchandise actually entered during the POR.

Cash Deposit Requirements

To calculate the cash deposit rate for each exporter, we divided the total dumping margins for each exporter by the total net value for that exporter's sales for each relevant class or kind of merchandise to the United States during the review period under each order.

In order to derive a single deposit rate for each class or kind of merchandise for each respondent (*i.e.*, each exporter or manufacturer included in these reviews), we weight-averaged the EP and CEP deposit rates (using the EP and CEP, respectively, as the weighting factors). To accomplish this where we sampled CEP sales, we first calculated the total dumping margins for all CEP sales during the review period by multiplying the sample CEP margins by the ratio of total weeks in the review period to sample weeks. We then calculated a total net value for all CEP sales during the review period by multiplying the sample CEP total net value by the same ratio. We then divided the combined total dumping margins for both EP and CEP sales by the combined total value for both EP and CEP sales to obtain the deposit rate.

We will direct Customs to collect the resulting percentage deposit rate against the entered Customs value of each of the exporter's entries of subject merchandise entered, or withdrawn from warehouse, for consumption on or after the date of publication of this notice.

Entries of parts incorporated into finished bearings before sales to an unaffiliated customer in the United States will receive the exporter's deposit rate for the appropriate class or kind of merchandise.

Furthermore, the following deposit requirements will be effective upon publication of this notice of final results of administrative reviews for all shipments of AFBs entered, or withdrawn from warehouse, for consumption on or after the date of publication, as provided by section 751(a)(1) of the Tariff Act: (1) The cash deposit rates for the reviewed companies will be the rates shown

above except that, for firms whose weighted-average margins are less than 0.5 percent and therefore *de minimis,* the Department shall require a zero deposit of estimated antidumping duties; (2) for previously reviewed or investigated companies not listed above, the cash deposit rate will continue to be the company-specific rate published for the most recent period; (3) if the exporter is not a firm covered in this review, a prior review, or the original less-than-fair-value (LTFV) investigation, but the manufacturer is, the cash deposit rate will be the rate established for the most recent period for the manufacturer of the merchandise; and (4) the cash deposit rate for all other manufacturers or exporters will continue to be the ''All Others'' rate for the relevant class or kind and country made effective by the final results of review published on July 26, 1993 (*see Final Results of Antidumping Duty Administrative Reviews and Revocation in Part of an Antidumping Duty Order,* 58 FR 39729 (July 26, 1993) and, for BBs from Italy, *see Antifriction Bearings (Other Than Tapered Roller Bearings) and Parts Thereof From France, et al: Final Results of Antidumping Duty Administrative Reviews, Partial Termination of Administrative Reviews, and Revocation in Part of Antidumping Duty Orders,* 61 FR 66472 (December 17, 1996)). These rates are the ''All Others'' rates from the relevant LTFV investigations.

These deposit requirements shall remain in effect until publication of the final results of the next administrative reviews.

This notice also serves as a final reminder to importers of their responsibility under 19 CFR 353.26 to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

This notice also serves as the only reminder to parties subject to administrative protective orders (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 353.34(d) or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

These administrative reviews and this notice are in accordance with section 751(a)(1) of the Tariff Act (19 U.S.C. 1675(a)(1)) and 19 CFR 353.22.

Dated: October 8, 1997.

Robert S. LaRussa,

Assistant Secretary for Import Administration.

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Scope Appendix

A. Description of the Merchandise

The products covered by these orders, antifriction bearings (other than tapered roller bearings), mounted or unmounted, and parts thereof (AFBs), constitute the following classes or kinds of merchandise:

1. *Ball Bearings and Parts Thereof:* These products include all AFBs that employ balls as the roller element. Imports of these products are classified under the following categories: antifriction balls, ball bearings with integral shafts, ball bearings (including radial ball bearings) and parts thereof, and housed or mounted ball bearing units and parts thereof. Imports of these products are classified under the following Harmonized Tariff Schedule (HTS) subheadings: 3926.90.45, 4016.93.00, 4016.93.10, 4016.93.50, 6909.19.5010, 8431.20.00, 8431.39.0010, 8482.10.10, 8482.10.50, 8482.80.00, 8482.91.00, 8482.99.05, 8482.99.35, 8482.99.2580, 8482.99.6595, 8483.20.40, 8483.20.80, 8483.50.8040, 8483.50.90, 8483.90.20, 8483.90.30, 8483.90.70, 8708.50.50, 8708.60.50, 8708.60.80, 8708.70.6060, 8708.70.8050, 8708.93.30, 8708.93.5000, 8708.93.6000, 8708.93.75, 8708.99.06, 8708.99.31, 8708.99.4960, 8708.99.50, 8708.99.5800, 8708.99.8080, 8803.10.00, 8803.20.00, 8803.30.00, 8803.90.30, and 8803.90.90.

2. *Cylindrical Roller Bearings, Mounted or Unmounted, and Parts Thereof:* These products include all AFBs that employ cylindrical rollers as the rolling element. Imports of these products are classified under the following categories: Antifriction rollers, all cylindrical roller bearings (including split cylindrical roller bearings) and parts thereof, housed or mounted cylindrical roller bearing units and parts thereof.

Imports of these products are classified under the following HTS subheadings: 3926.90.45, 4016.93.00, 4016.93.10, 4016.93.50, 6909.19.5010, 8431.20.00, 8431.39.0010, 8482.40.00, 8482.50.00, 8482.80.00, 8482.91.00, 8482.99.25, 8482.99.35, 8482.99.6530, 8482.99.6560, 8482.99.70, 8483.20.40, 8483.20.80, 8483.50.8040, 8483.90.20, 8483.90.30, 8483.90.70, 8708.50.50, 8708.60.50, 8708.93.5000, 8708.99.4000, 8708.99.4960, 8708.99.50, 8708.99.8080, 8803.10.00, 8803.20.00, 8803.30.00, 8803.90.30, and 8803.90.90.

3. *Spherical Plain Bearings, Mounted or Unmounted, and Parts Thereof:* These products include all spherical plain bearings that employ a spherically shaped sliding element, and include spherical plain rod ends.

Imports of these products are classified under the following HTS subheadings: 3926.90.45, 4016.93.00, 4016.93.00, 4016.93.10, 4016.93.50, 6909.50,10, 8483.30.80, 8483.90.30, 8485.90.00, 8708.93.5000, 8708.99.50, 8803.10.00, 8803.10.00, 8803.20.00, 8803.30.00, and 8803.90.90.

The HTS item numbers are provided for convenience and customs purposes. They are not determinative of the products subject to the orders. The written description remains dispositive.

Size or precision grade of a bearing does not influence whether the bearing is covered by the orders. These orders cover all the subject bearings and parts thereof (inner race, outer race, cage, rollers, balls, seals, shields, etc.)

outlined above with certain limitations. With regard to finished parts, all such parts are included in the scope of these orders. For unfinished parts, such parts are included if (1) they have been heat-treated, or (2) heat treatment is not required to be performed on the part. Thus, the only unfinished parts that are not covered by these orders are those that will be subject to heat treatment after importation.

The ultimate application of a bearing also does not influence whether the bearing is covered by the orders. Bearings designed for highly specialized applications are not excluded. Any of the subject bearings, regardless of whether they may ultimately be utilized in aircraft, automobiles, or other equipment, are within the scope of these orders.

B. Scope Determinations

The Department has issued numerous clarifications of the scope of the orders. The following is a compilation of the scope rulings and determinations the Department has made:

Scope determinations made in the *Final Determinations of Sales at Less than Fair Value; Antifriction Bearings (Other Than Tapered Roller Bearings) and Parts Thereof from the Federal Republic of Germany*, 54 FR 19006, 19019 (May 3, 1989):

Products covered:

- Rod end bearings and parts thereof.
- AFBs used in aviation applications.
- Aerospace engine bearings.
- Split cylindrical roller bearings.
- Wheel hub units.
- Slewing rings and slewing bearings (slewing rings and slewing bearings were subsequently excluded by the International Trade Commission's negative injury determination (*see International Trade Commission: Antifriction Bearings (Other Than Tapered Roller Bearings) and Parts Thereof from the Federal Republic of Germany, France, Italy, Japan, Romania, Singapore, Sweden, Thailand and the United Kingdom*, 54 FR 21488 (May 18, 1989)).
- Wave generator bearings.
- Bearings (including mounted or housed units and flanged or enhanced bearings) ultimately utilized in textile machinery.

Products excluded:

- Plain bearings other than spherical plain bearings.
- Airframe components unrelated to the reduction of friction
- Linear motion devices.
- Split pillow block housings.
- Nuts, bolts, and sleeves that are not integral parts of a bearing or attached to a bearing under review.
- Thermoplastic bearings.
- Stainless steel hollow balls.
- Textile machinery components that are substantially advanced in function(s) or value.
- Wheel hub units imported as part of front and rear axle assemblies; wheel hub units that include tapered roller bearings; and clutch release bearings that are already assembled as parts of transmissions.

Scope rulings completed between April 1, 1990, and June 30, 1990 (*see Scope Rulings*, 55 FR 42750 (October 23, 1990)):

Products excluded:

- Antifriction bearings, including integral shaft ball bearings, used in textile machinery and imported with attachments and augmentations sufficient to advance their function beyond load-bearing/friction-reducing capability.

Scope rulings completed between July 1, 1990, and September 30, 1990 (*see Scope Rulings*, 55 FR 43020 (October 25, 1990)):

Products covered:

- Rod ends.
- Clutch release bearings.
- Ball bearings used in the manufacture of helicopters.
- Ball bearings used in the manufacture of disk drives.

Scope rulings published in *Antifriction Bearings (Other Than Tapered Roller Bearings) and Parts Thereof; Final Results of Antidumping Administrative Review (AFBs I)*, 56 FR 31692, 31696 (July 11, 1991):

Products covered:

- Load rollers and thrust rollers, also called mast guide bearings.
- Conveyor system trolley wheels and chain wheels.

Scope rulings completed between April 1, 1991, and June 30, 1991 (*see Notice of Scope Rulings*, 56 FR 36774 (August 1, 1991)):

Products excluded:

- Textile machinery components including false twist spindles, belt guide rollers, separator rollers, damping units, rotor units, and tension pulleys.

Scope rulings completed between July 1, 1991, and September 30, 1991 (*see Scope Rulings*, 56 FR 57320 (November 8, 1991)):

Products covered:

- Snap rings and wire races.
- Bearings imported as spare parts.
- Custom-made specialty bearings.

Products excluded: .

- Certain rotor assembly textile machinery components.
- Linear motion bearings.

Scope rulings completed between October 1, 1991, and December 31, 1991 (*see Notice of Scope Rulings*, 57 FR 4597 (February 6, 1992)):

Products covered:

- Chain sheaves (forklift truck mast components).
- Loose boss rollers used in textile drafting machinery, also called top rollers.
- Certain engine main shaft pilot bearings and engine crank shaft bearings.

Scope rulings completed between January 1, 1992, and March 31, 1992 (*see Scope Rulings*, 57 FR 19602 (May 7, 1992)):

Products covered:

- Ceramic bearings.
- Roller turn rollers.
- Clutch release systems that contain rolling elements.

Products excluded:

- Clutch release systems that do not contain rolling elements.
- Chrome steel balls for use as check valves in hydraulic valve systems.

Scope rulings completed between April 1, 1992, and June 30, 1992 (*see Scope Rulings*, 57 FR 32973 (July 24, 1992)):

Products excluded:

- Finished, semiground stainless steel balls.
- Stainless steel balls for non-bearing use (in an optical polishing process).

Scope rulings completed between July 1, 1992, and September 30, 1992 (*see Scope Rulings*, 57 FR 57420 (December 4, 1992)):

Products covered:

- Certain flexible roller bearings whose component rollers have a length-to-diameter ratio of less than 4:1.
- Model 15BM2110 bearings.

Products excluded:

- Certain textile machinery components.

Scope rulings completed between October 1, 1992, and December 31, 1992 (*see Scope Rulings*, 58 FR 11209 (February 24, 1993)):

Products covered:

- Certain cylindrical bearings with a length-to-diameter ratio of less than 4:1.

Products excluded:

- Certain cartridge assemblies comprised of a machine shaft, a machined housing and two standard bearings.

Scope rulings completed between January 1, 1993, and March 31, 1993 (*see Scope Rulings*, 58 FR 27542 (May 10, 1993)):

Products covered:

- Certain cylindrical bearings with a length-to-diameter ratio of less than 4:1.

Scope rulings completed between April 1, 1993, and June 30, 1993 (*see Scope Rulings*, 58 FR 47124 (September 7, 1993)):

Products covered:

- Certain series of INA bearings.

Products excluded:

- SAR series of ball bearings.
- Certain eccentric locking collars that are part of housed bearing units.

Scope rulings completed between October 1, 1993, and December 31, 1993 (*see Scope Rulings,* 59 FR 8910 (February 24, 1994)):

Products excluded:

- Certain textile machinery components.

Scope rulings completed between January 1, 1994, and March 31, 1994:

Products excluded:

- Certain textile machinery components.

Scope rulings completed between October 1, 1994 and December 31, 1994 (*see Scope Rulings,* 60 FR 12196 (March 6, 1995)):

Products excluded:

- Rotek and Kaydon—Rotek bearings, models M4 and L6, are slewing rings outside the scope of the order.

Scope rulings completed between April 1, 1995 and June 30, 1995 (*see Scope Rulings,* 60 FR 36782 (July 18, 1995)):

Products covered:

- Consolidated Saw Mill International (CSMI) Inc.—Cambio bearings contained in CSMI's sawmill debarker are within the scope of the order.
- Nakanishi Manufacturing Corp.—Nakanishi's stamped steel washer with a zinc phosphate and adhesive coating used in the manufacture of a ball bearing is within the scope of the order.

Scope rulings completed between January 1, 1996 and March 31, 1996 (*see Scope Rulings,* 61 FR 18381 (April 25, 1996)):

Products covered:

- Marquardt Switches—Medium carbon steel balls imported by Marquardt are outside the scope of the order.

Scope rulings completed between April 1, 1996 and June 30, 1996 (*see Scope Rulings,* 61 FR 40194 (August 1, 1996)):

Products excluded:

- Dana Corporation—Automotive component, known variously as a center bracket assembly, center bearings assembly, support bracket, or shaft support bearing, is outside the scope of the order.
- Rockwell International Corporation—Automotive component, known variously as a cushion suspension unit, cushion assembly unit, or center bearing assembly, is outside the scope of the order.
- Enkotec Company, Inc.—''Main bearings'' imported for incorporation into Enkotec Rotary Nail Machines are slewing rings and, therefore, are outside the scope of the order.

Issues Appendix

Company Abbreviations

Barden—Barden Corporation (U.K.) Ltd. and the Barden Corporation
FAG Germany—FAG Kugelfischer Georg Schaefer KGaA
FAG Italy—FAG Italia S.p.A.; FAG Bearings Corp.
FAG U.K.—FAG (U.K.) Ltd.
INA—INA Walzlager Schaeffler KG; INA Bearing Company, Inc.
Koyo—Koyo Seiko Co. Ltd.
Nachi—Nachi-Fujikoshi Corp., Nachi America Inc. and Nachi Technology, Inc.
NMB/Pelmec—NMB Singapore Ltd.; Pelmec Industries (Pte.) Ltd.
NPBS—Nippon Pillow Block Manufacturing Co., Ltd.; Nippon Pillow Block Sales Co., Ltd.; FYH Bearing Units USA, Inc.
NSK—Nippon Seiko K.K.; NSK Corporation
NSK-RHP—NSK Bearings Europe, Ltd.; RHP Bearings; RHP Bearings, Inc.
NTN Germany—NTN Kugellagerfabrik (Deutschland) GmbH
NTN Japan—NTN Corporation; NTN Bearing Corporation of America; American NTN Bearing Manufacturing Corporation
SKF France—SKF Compagnie d'Applications Mecaniques, S.A. (Clamart); ADR; SARMA
SKF Germany—SKF GmbH; SKF Service GmbH; Steyr Walzlager
SKF Italy—SKF Industrie; RIV-SKF Officina de Villar Perosa; SKF Cuscinetti Speciali; SKF Cuscinetti; RFT
SKF Group—SKF-France; SKF-Germany; SKF-Italy; SKF-Sweden; SKF USA, Inc.
SKF Sweden—SKF Sverige AB
SNFA—SNFA Bearings, Ltd.
SNR France—SNR Nouvelle Roulements
TIE—Tehnoimportexport
Torrington—The Torrington Company

Other Abbreviations

COP—Cost of Production
COM—Cost of Manufacturing
CV—Constructed Value
CEP—Constructed Export Price
NV—Normal Value
HM—Home Market
OEM—Original Equipment Manufacturer
POR—Period of Review
PSPA—Post-Sale Price Adjustment
SAA—Statement of Administrative Action
URAA—Uruguay Round Agreements Act

AFB Administrative Determinations

LTFV Investigation—Final Determinations of Sales at Less than Fair Value; Antifriction Bearings (Other Than Tapered Roller Bearings) and Parts Thereof from the Federal Republic of Germany, 54 FR 19006 (May 3, 1989).

AFBs I—Antifriction Bearings (Other Than Tapered Roller Bearings) and Parts Thereof from the Federal Republic of Germany; Final Results of Antidumping Duty Administrative Review, 56 FR 31692 (July 11, 1991).

AFBs II—Antifriction Bearings (Other Than Tapered Roller Bearings) and Parts Thereof From France, et al.; Final Results of Antidumping Duty Administrative Reviews, 57 FR 28360 (June 24, 1992).

AFBs III—Antifriction Bearings (Other Than Tapered Roller Bearings) and Parts Thereof From France, et al.; Final Results of Antidumping Duty Administrative Reviews and Revocation in Part of an Antidumping Duty Order, 58 FR 39729 (July 26, 1993).

AFBs IV—Antifriction Bearings (Other Than Tapered Roller Bearings) and Parts Thereof From France, et al; Final Results of Antidumping Duty Administrative Reviews, Partial Termination of Administrative Reviews, and Revocation in Part of Antidumping Duty Orders, 60 FR 10900 (February 28, 1995).

AFBs V—Antifriction Bearings (Other Than Tapered Roller Bearings) and Parts Thereof From France, et al; Final Results of Antidumping Duty Administrative Reviews and Partial Termination of Administrative Reviews, 61 FR 66472 (December 17, 1996).

AFBs VI—Antifriction Bearings (Other Than Tapered Roller Bearings) and Parts Thereof From France, et al; Final Results of Antidumping Duty Administrative Reviews and Partial Termination of Administrative Reviews, 62 FR 2081 (January 15, 1997).

1. Facts Available

Comment: SKF France maintains that, with respect to its CRBs, the Department had no basis upon which to make an adverse inference since SKF companies did not sell French CRBs to the United States during this review period and since in its questionnaire responses it stated that SKF France did not make such sales. SKF France maintains that its response demonstrates that only BBs and SPBs were subject to review and, further, that SKF's reporting of HM and U.S. sales of SKF's French AFBs has been verified consistently. Finally, SKF France argues that, because the Department's use of facts available and an adverse inference is inappropriate as to CRBs, it is also inappropriate as to duty absorption by SKF with respect to CRBs.

Department's Position: We agree with SKF France. We sent a no-shipment inquiry to U.S. Customs on March 24, 1997. Customs did not indicate that there were any entries of CRBs from SKF France. Without such entries during the review period, there is nothing upon which we may assess any duties we determine in the course of the review. Therefore, the issue of whether SKF France had any sales of CRBs is moot.

In addition, we will continue to apply the ''all others'' rate, which is the rate established in the LTFV investigation, to CRBs from France for future entries of this merchandise. Because we are not applying facts available to SKF France's CRBs, we have not applied facts available in our duty-absorption determination on CRBs from SKF France.

2. Discounts, Rebates, and Price Adjustments

We have accepted claims for discounts, rebates, and other billing adjustments as direct adjustments to price if we determined that the respondent, in reporting these adjustments, acted to the best of its ability and that its reporting methodology was not unreasonably distortive. We did not treat such adjustments as direct (or indirect) selling expenses but, rather, as direct adjustments necessary to identify the correct starting price. While we prefer that respondents report these adjustments on a transaction-specific basis (or, where a single adjustment was granted for a group of sales, as a fixed and constant percentage of the value of those sales), we recognize that this is not always feasible, particularly given the extremely large volume of transactions involved in these AFBs reviews. It is inappropriate to reject allocations that are not unreasonably distortive in favor of facts otherwise available where a fully cooperating respondent is unable to report the information in a more specific manner. *See* section 776 of the Tariff Act. Accordingly, we have accepted these adjustments when it was not feasible for a respondent to report the adjustment on a more specific basis, provided that the allocation method the respondent used does not cause unreasonable inaccuracies or distortions.

In applying this standard, we have not rejected an allocation method solely because the allocation includes adjustments granted on merchandise that is not subject to these reviews (out-of-scope merchandise). However, such allocations are not acceptable where we have reason to believe that respondents did not grant such adjustments in proportionate amounts with respect to sales of out-of-scope and in-scope merchandise. We have made this determination by examining the extent to which the out-of-scope merchandise included in the allocation pool is different from the in-scope merchandise in terms of value, physical characteristics, and the manner in which it is sold. Significant differences in such areas may increase the likelihood that respondents did not grant price adjustments in proportionate amounts with respect to sales of in-scope and out-of-scope merchandise. While we scrutinize any such differences carefully between in-scope and out-of-scope sales in terms of their potential for distorting reported per-unit adjustments on the sales involved in our analysis, it would not be reasonable to require that respondents submit sale-specific adjustment data on out-of-scope merchandise in order to prove that there is no possibility for distortion. Such a requirement would defeat the purpose of permitting the use of reasonable allocations by a respondent that has cooperated to the best of its ability.

Where we have found that a company has not acted to the best of its ability in reporting the adjustment in the most specific and non-distortive manner feasible, we have made an adverse inference in using the facts available with respect to this adjustment pursuant to section 776(b) of the Tariff Act. With respect to HM adjustments, in accordance with the Court of Appeals for the Federal Circuit's (CAFC) decision in *The Torrington Company* v. *United States*, 82 F.3d 1039, 1047–51 (CAFC 1996) (*Torrington I*) , we have not treated improperly allocated HM price adjustments as if they were indirect selling expenses (ISEs), but we have instead disallowed downward adjustments in their entirety. However, we have included positive (upward) HM price adjustments (*e.g.*, positive billing adjustments that increase the final sales price) in our analysis of such companies. The treatment of positive HM billing adjustments as direct adjustments is appropriate because disallowing such adjustments would provide an incentive to report positive billing adjustments on an unacceptably broad basis in order to reduce NV and margins. That is, if we were to disregard positive billing adjustments, which would be upward adjustments to NV, respondents would have no incentive to report these adjustments in the most specific and non-distortive manner feasible. *See AFBs V* at 66498.

Comment 1: Torrington asserts that some respondents reported home-market discounts, rebates, and post-sale price adjustments (PSPAs) by allocating amounts across all sales or across all sales to a given customer, even when some sales were not entitled to the adjustment. Torrington cites the CAFC's decision in *Torrington I* (at 1047–51), arguing that direct PSPAs must be reported on a sale-specific basis in order for the Department to make a downward adjustment to NV and that the Department may not make an adjustment for improperly allocated direct expenses as if these were indirect expenses. Torrington contends that the new statute retains the distinction between direct and indirect selling expenses, citing sections 772(d)(1)(B) and (D) and section 773(a)(7)(B) of the Tariff Act. Petitioner argues that, while the discussion in the SAA at 823–824 demonstrates the intention to continue the practice of allowing allocations when allocations were non-distortive, this statement is no longer valid because it was written in 1994, prior to *Torrington I*, when the Administration held the belief that its practice was sustained by the courts. Therefore, Torrington asserts, the Department should deny all rebates, discounts, and PSPAs that respondents did not report on a transaction-specific basis or which they did not allocate in such a manner as to be tantamount to reporting on a transaction-specific basis.

FAG, Koyo, Nachi, NSK, and SKF argue that the Department should make direct adjustments to price when the allocation of PSPAs is reasonable and not distortive and that such practice conforms with the SAA and the new regulations at 351.401(g)(1). Koyo, Nachi, NSK, and SKF contend that, in *Torrington I*, the CAFC did not disallow an adjustment merely because it involved an allocation. According to respondents, the court stated that, regardless of the allocation method, the Department could not treat direct price adjustments as indirect selling expenses, but the court did not address the propriety of the allocation methodology. Additionally, respondents claim, the allocation of these expenses does not detract from their relation to particular transactions, thereby making them direct expenses and deductible from price.

NSK further argues that the Department need not disallow price adjustments simply because the respondent is unable to report these expenses on a sales-specific basis (citing *Smith-Corona* v. *United States*, 713 F. 2d 1568, 1580 (CAFC 1983)). Additionally, Koyo argues that the Department treated the PSPAs properly as direct adjustments to gross price,

rather than as direct or indirect selling expenses, since they are corrections to the sales price and do not arise as a result of preparing the merchandise for sale or from selling activities.

NTN contends it reported such adjustments on a transaction-specific basis. Therefore, NTN claims that Torrington's arguments do not apply to its response.

Department's Position: We agree with FAG, Koyo, Nachi, NSK, SKF, and NTN. As we discussed in the introductory remarks to this section, our practice is not to reject an allocation of price adjustments when it was not feasible for a respondent to report the adjustments on a more specific basis, provided that the allocation method the respondent used does not cause unreasonable inaccuracies or distortions.

We see no conflict between *Torrington I* and our acceptance of allocated price adjustments subject to the above conditions because the CAFC did not address the propriety of the allocation methods respondents used in reporting the price adjustments in question. Although the CAFC appeared to question whether price adjustments constituted expenses at all (see *Torrington I* at n.15), it held that, assuming the adjustments were expenses, they had to be treated as direct selling expenses and could not be used to offset the deduction of U.S. indirect selling expenses. The CAFC did not find that such price adjustments could not be based on allocations. In fact, such a holding would have been inconsistent with the CAFC's prior holding in *Smith-Corona Group* v. *United States,* 713 F. 2d 1568, 1580–81 (CAFC 1983), which the *Torrington I* court did not question.

Comment 2: Torrington asserts that, if the Department accepts allocated PSPAs as a direct adjustment to NV in these reviews, it should not follow the method it used in the 1994/95 administrative reviews to determine whether the allocations are distortive. Rather, Torrington argues, the Department should judge all allocations using product-specific sales information. Torrington notes that different classes or kinds of AFBs cannot be deemed similar for purposes of expense allocations because the Department found in the original less-than-fair-value proceeding that there are several ''classes or kinds'' of bearings, each requiring a separate proceeding. Torrington explains that the physical characteristics of non-subject merchandise should not be considered similar to those of subject merchandise for purposes of expense allocations. Torrington argues that, if the physical characteristics of an out-of-scope bearing are considered similar to those of an in-scope bearing for purposes of allocating price adjustments, then the former should be included within the scope of the order.

FAG, Koyo, NSK, and SKF assert that the Department's 1994/95 review methodology used to determine the distortiveness of the allocation of PSPAs is sufficient. These respondents contend that the Department has reviewed the propriety of their allocation methodologies correctly by considering those products receiving allocated expenses according to the value and physical characteristics of the products and the manner in which they were sold. FAG, Koyo, NSK, and SKF contend that there is no evidence that the Department's methodology allowed disproportionate allocations of PSPAs across subject and non-subject merchandise and conclude that the Department should continue their use.

NTN asserts that Torrington's argument concerning the Department's methodology for determining distortiveness of allocations does not apply to it because it reported discounts on a product-specific basis.

Department's Position: We agree with FAG, Koyo, NSK, NTN, and SKF. As stated above in the introductory remarks to this section, in determining the propriety of respondents' allocation methodologies for price adjustments, we have not rejected an allocation method solely because the allocation includes adjustments granted on merchandise that is not subject to these reviews (out-of-scope merchandise). However, we did not accept such allocations where we had reason to believe that a respondent granted such adjustments in disproportionate amounts with respect to sales of out-of-scope and in-scope merchandise. We have made this determination by examining the extent to which the out-of-scope merchandise included in the allocation pool is different from the in-scope merchandise in terms of value, physical characteristics, and the manner in which it was sold. Significant differences in such areas may increase the likelihood that respondents granted price adjustments in disproportionate amounts with respect to sales of in-scope and out-of-scope merchandise.

Comment 3: Torrington contends that the Department should disallow certain discounts NTN Japan reported. Torrington argues that, based on documentation the Department obtained at verification which relates to the negotiation of certain discounts, NTN Japan's reported discounts were not granted on a customer-and product-specific basis and were not limited to subject merchandise. In addition, Torrington asserts that evidence on record indicates that these adjustments may not be discounts but, rather, may be claims for a different kind of adjustment for which, Torrington asserts, NTN has not met the Departmental standard.

NTN Japan maintains that negotiating discounts is a part of its normal business activity and that the Department verified its reported discounts in detail and found that they were granted on a customer-and product-specific basis. NTN asserts that Torrington's argument is based improperly on limited documentation included on the record and it fails to consider the overall verification by the Department officials, which included the examination of numerous documents relevant to these discounts which were not entered on the record. NTN notes that the Department is not required to enter all documents examined during verification on the record.

Department's Position: We disagree with the petitioner. We verified this discount and found that NTN granted it ''by product for each customer.'' In addition, it meets the Department's standard for a discount. We reached this conclusion after reviewing numerous documents at verification, although we did not include all reviewed information was included in the record as a verification exhibit. (*See* Verification Report dated May 8, 1997, at 5.) Therefore, petitioner's argument regarding whether the discount should be treated as something other than a discount is incorrect.

Comment 4: Koyo contends that the Department correctly accepted one of its billing adjustment claims (designated BILADJ1H in the response) but inexplicably failed to accept the other billing adjustment claim (designated BILADJ2H in the response). Koyo contends that both billing adjustments have been accepted in past AFB and tapered roller bearing (TRB) administrative reviews and that there have been no changes in its reporting methodology since the completion of those reviews.

Torrington argues that both of Koyo's billing adjustments, which it reported on a customer-specific basis, should be rejected. Torrington contends that BILADJ1H, which it claims was granted on a model-specific basis but was reported on a customer-specific basis, and BILADJ2H, which it claims was granted on a lump-sum basis, should both be rejected as both reporting methods result in the application of

price adjustments to transactions which were not subject to these adjustments.

Department's Position: With respect to BILADJ1H, Koyo granted the adjustment amount on a customer- and model-specific basis. Koyo then totaled the price adjustments granted and sales of subject merchandise sold to each customer to calculate an overall adjustment factor per customer in order to allocate the adjustment over subject merchandise sales to the respective customer. Our examination of the record leads us to conclude that, while Koyo has paper records of the adjustment, it is not feasible for Koyo to retrieve the information electronically or to allocate this adjustment more specifically, given the large volume of transactions involved, the level of detail contained in Koyo's normal accounting records, and the time constraints imposed by the statutory deadlines under which all parties must operate. Therefore, we have accepted Koyo's reporting methodology for these billing adjustments.

With respect to BILADJ2H, Koyo granted both lump-sum adjustments which it negotiated with its customers without reference to model-specific selling prices and some adjustments which it granted on a model-specific basis but which Koyo reported on a customer-specific basis. Koyo allocated BILADJ2H to subject merchandise on the basis of sales value.

We have reconsidered our disallowance of BILADJ2H for the preliminary results and now agree with Koyo that we should allow its lump-sum billing adjustments as a direct adjustments to NV. We determine that Koyo acted to the best of its ability in reporting this information using customer-specific allocations. Given the fact that Koyo's records do not readily identify a discrete group of sales to which each billing adjustment pertains and the extremely large number of POR sales Koyo made, it is not feasible for Koyo to report this adjustment on a more specific basis. Moreover, we are satisfied that Koyo's allocation methodology across subject merchandise by sales value was not distortive.

Comment 5: Torrington argues that FAG Germany reported HM rebates improperly. Torrington notes that, while some rebates were payable only in connection with purchases of certain types of products, FAG reported these rebates on a customer-specific basis, creating the likelihood that some rebates were reported on sales when no rebates were actually paid. For this reason, Torrington asserts that the Department should deny the claimed adjustment.

FAG argues that it reported all rebates properly so that no rebates were reported where they did not apply. For customer-specific rebates, FAG claims it reported instances where the rebate was applicable to only certain products and factored the rebate only over sales of those products.

Department's Position: We disagree with Torrington. As Exhibit B–6 of FAG's questionnaire response dated September 9, 1996 demonstrates, FAG allocated its rebates on a customer-specific basis over sales only of those products that actually received rebates. Therefore, we determine that FAG's methodology for reporting rebates is reasonable and not distortive, and, in accordance with our policy, we have accepted FAG's HM rebates as reported.

Comment 6: Torrington argues that the Department should disallow certain post-sale price adjustments which SKF Germany reported in an inaccurate manner. Torrington contends that SKF Germany reported support rebates to distributors in a manner different from the manner in which the rebate was actually granted and, therefore, the Department should reject the adjustment to price. Torrington purports that, whereas SKF determines eligibility by comparing SKF Germany's invoice price to the reseller's invoice price, the reporting methodology allocates the rebate across all sales to the reseller, thereby reporting rebates on sales where none actually occurred.

Additionally, Torrington argues that the Department should reject SKF Germany's billing adjustment 2 in the HM, as it was not reported in an accurate manner. Petitioner contends that customer-specific reporting of the adjustment is not accurate unless the adjustment applies equally to all sales to that customer. Torrington also asserts that SKF did not report the timing of such billing adjustments accurately. Furthermore, Torrington points out that SKF was able to report such billing adjustments on a transaction-specific basis for U.S. sales but did not explain why it was unable to report the same adjustment on a transaction-specific basis for HM sales.

Finally, Torrington claims that it should not be responsible for demonstrating the distortive nature of such allocations because it does not have access to information which would allow such demonstration. Torrington maintains that it is SKF Germany's responsibility to produce evidence to demonstrate that its methodology is not distortive. Torrington concludes that, while the Department requested additional information for purposes of determining the distortiveness of such allocations, SKF Germany responded in a general, non-specific manner, precluding such a judgment by the Department.

SKF Germany argues that the Department was correct in accepting support rebates and billing adjustment 2 as adjustments to HM price. SKF Germany contends that Torrington is incorrect in arguing that SKF's reporting methodology regarding support rebates is likely to result in rebates on sales where none actually occurred. SKF Germany notes that, for each customer for whom SKF reported a support rebate, it actually granted a rebate to that customer and the actual amount granted does relate to the totality of sales to that customer. SKF Germany argues that the allocation of the rebate on aggregate sales to that customer is proper since the amount is based on sales of the customer, not sales of SKF Germany to the customer. As such, SKF states that it reported the rebate in exactly the manner in which it was incurred.

SKF Germany also disagrees with Torrington concerning billing adjustment 2, arguing that this billing adjustment applies only in instances where transaction-specific attribution was not possible. SKF disagrees further with Torrington's argument that SKF USA's ability to report billing adjustments on a transaction-specific manner supports Torrington's contention that the adjustment should be disallowed in the HM. Rather, SKF contends this difference in reporting methodology supports the allowance of SKF Germany's billing adjustment 2 because it demonstrates the two types of billing adjustments the two companies made. SKF USA only grants transaction-specific billing adjustments (billing adjustment 1), while SKF Germany grants rebates associated with a specific transaction (billing adjustment 1) and those that are not linked with a particular transaction (billing adjustment 2).

Department's Position: We agree with SKF Germany regarding our treatment of support rebates and billing adjustment 2. We find that SKF Germany's allocation methodologies are not unreasonably distortive. Due to the nature of the support rebates, transaction-specific reporting is not appropriate. SKF Germany grants these rebates to distributors/dealers to ensure that they obtain a minimum profit level on sales to select customers. Hence, because SKF Germany does not issue these rebates based on specific sales to the distributor/dealers but rather on the sales of the distributors/dealers, SKF Germany cannot report transaction-

specific rebate amounts. Rather, SKF Germany has allocated the rebates it granted to a specific customer over all sales to that customer. SKF Germany's allocation methodology is not unreasonably distortive, as we are satisfied that each adjustment was granted in proportionate amounts with respect to the value of sales of in-scope and out-of-scope merchandise.

With respect to billing adjustment 2, SKF Germany reported billing adjustments not associated with a specific transaction. SKF Germany could not tie these adjustments to a specific transaction because the billing adjustments it reported in this field were part of credit or debit notes, issued to the customer, that related to multiple invoices, products, or invoice lines. In these cases, the most feasible reporting methodology that SKF Germany could use was a customer-specific allocation, given the large volume of transactions involved in these AFB reviews and the time constraints imposed by the statutory deadlines. Furthermore, we found that the products which received the adjustment were similar in terms of value, physical characteristics, and the manner in which they were sold. For these reasons, we find that this methodology is not unreasonably distortive.

We agree with Torrington that it should not be responsible for demonstrating the distortive nature of this allocation; rather it is the responsibility of the respondent to demonstrate that its methodology is not unreasonably inaccurate or distortive. SKF Germany has satisfied this responsibility with regard to the reporting of its support rebates and billing adjustment 2 with adequate explanation in its response. SKF Germany demonstrated that its allocation methodology was reasonable and that the AFB products over which it allocated a PSPA were similar in terms of value, physical characteristics and the method in which they were sold.

Comment 7: INA argues that the Department did not transfer negative billing adjustments from the HM sales database submitted by INA to the HM sales file used for the preliminary results, since the Department did not include in its preliminary results calculations the negative billing adjustments INA reported in the Department's preliminary results calculations. INA claims that this is a clerical error and that this error should be corrected in the final results.

In rebuttal, Torrington contends that the Department should disallow all of INA's claimed downward billing adjustments in calculating NV because INA provided only a brief description of its HM billing adjustments which did not indicate whether the adjustments were limited to in-scope merchandise. Torrington argues that the CAFC held that direct PSPAs must be reported on a sale-specific basis before the Department can make a downward adjustment in calculating NV.

Department's Position: We disagree with INA. We do not view the omission of downward HM billing adjustments as a clerical error and have disallowed this adjustment for the final results. As we discussed in the introductory remarks to this section, our practice is to accept claims for discounts, rebates, and other billing adjustments as direct adjustments to price if we determined that the respondent, in reporting these adjustments, acted to the best of its ability and that its reporting methodology was not unreasonably distortive (see section 776 of the Tariff Act).

In our supplemental questionnaire dated January 23, 1997, we requested specifically that INA provide additional information to explain and demonstrate the nature of its reported billing adjustments and how they were incurred and recorded in INA's accounting system, as well as to demonstrate that the allocations were not unreasonably distortive. In INA's February 12, 1997 supplemental questionnaire response at page 16, the firm provided only a brief description of its HM billing adjustments by stating that all were made strictly on a transaction-specific basis and were made in cases in which INA Germany had to correct billing errors and in cases where the prices were definitely agreed upon with the customers after the shipments. However, INA did not provide sufficient evidence to demonstrate that the allocations of downward billing adjustments were limited to in-scope merchandise or were not otherwise unreasonably distortive. Because there is nothing on the record to support the accuracy of INA's claim, we have denied the adjustment.

As we mentioned in the introductory remarks at the beginning of this section, when we reject a respondent's allocation of price adjustments, we only reject the downward adjustments to NV. Therefore for these final results, we have included INA's upward billing adjustments in our analysis.

3. Circumstance-of-Sale Adjustments

3.A. Technical Services and Warranty Expenses

Comment 1: Torrington argues that the Department should treat certain of NTN's U.S. technical service expenses as direct rather than indirect selling expenses. Torrington asserts that NTN's supplemental questionnaire response did not meet the burden of demonstrating the indirect nature of the technical service expenses and, therefore, maintains that the Department should treat such expenses as direct selling expenses.

NTN argues that it responded adequately to the Department's supplemental inquiries regarding NTN's reported U.S. technical service expenses and notes that Torrington misread the question the Department posed in its supplemental questionnaire. NTN argues further that, if the Department determined that the technical service information provided in its responses did not demonstrate the indirect nature of such expenses, the Department would have requested NTN to submit additional information. NTN maintains that the manner in which it reported the expense in these reviews is based on the same methodology with which it reported the expense in the 94/95 administrative reviews and states that, in those reviews, the Department accepted NTN's methodology of reporting this expense.

Department's Position: We disagree with Torrington. In its supplemental response, NTN explained that the expenses are fixed expenses and do not vary with sales volumes. Therefore, because we are satisfied with NTN's responses to our questions, we have treated these expenses as indirect in nature.

Comment 2: Torrington asserts that SKF Germany under-reported its direct warranty expenses with regard to U.S. sales and that the Department should recalculate the direct adjustment to U.S. prices for warranty claims, including a facts-available amount for additional expenses which SKF Germany did not report properly. Torrington explains that, while SKF Germany reported the cost of replacement bearings as a direct warranty expense in the U.S. market, elsewhere in its response SKF Germany describes that in its warranty activities it incurs expenses associated with ''customer contact, processing warranty claims, testing of bearings, and directing the shipment of defective and replacement bearings.'' Therefore, petitioner claims, SKF Germany incurs direct expenses other than merely the replacement cost of bearings and the

Department must account for these expenses in its calculations.

SKF Germany disagrees with Torrington's contention that direct warranty expenses for SKF USA were under-reported and that the Department should apply facts available, arguing that certain expenses which Torrington considers to be direct are indirect expenses and were reported properly as such.

Department's Position: We disagree with Torrington. Based on our analysis of the information SKF Germany submitted in these reviews, we agree with SKF Germany that it referred to fixed types of expense activities correctly, such as salary expenses for customer service representatives and salesmen who make customer contacts and process warranty claims as well as salary expenses for application engineers who test bearings and other internal testing expenses, as indirect expenses. Because these are fixed expenses, it was proper to report them as indirect expenses. Because there are no other issues with respect to SKF Germany's reporting of its U.S. direct warranty expenses, we have accepted SKF Germany's U.S. direct warranty expenses as reported for these final results.

3.B. Credit

Comment 1: Torrington contends that the adjusted price SKF Germany used to calculate credit expenses in the HM differed in its adjustments from the adjusted price used to calculate credit expenses in the U.S. market. According to Torrington, the adjusted price SKF Germany used in the U.S. market calculation included a deduction of cash discounts from the gross unit price incorrectly, though the HM adjusted price did not reflect such a deduction. Torrington contends that, because the calculation in the U.S. market was therefore lower, the result is an under-reporting of U.S. credit expenses. Because SKF Germany reported cash discounts in both the United States and the HM, Torrington asserts that the Department should recalculate reported credit expenses using fully adjusted prices in the calculation or apply facts-available information.

SKF Germany argues that it has not changed its methodology of calculating credit expense from that it used in prior reviews and notes that the Department has accepted it in prior reviews.

Department's Position: We agree with Torrington. SKF Germany calculated U.S. credit expense based on prices net of cash discounts but did not include deductions for reported cash discounts in the adjustment of prices SKF Germany used for calculation of HM credit expense. We have recalculated SKF Germany's HM credit expenses based on adjusted prices net of discounts for these final results.

Comment 2: Torrington contends that the Department should recalculate NTN's U.S. credit expense because NTN reported a customer-specific average credit expense rather than a transaction-specific credit expense. Torrington argues that reporting credit expense on an average basis may be distortive in cases where not all U.S. sales are dumped. Torrington points out that NTN has provided the necessary information on the record to recalculate a transaction-specific credit expense.

NTN rebuts Torrington's argument that its credit expense should be recalculated and points out that the Department has accepted NTN's methodology of reporting an average credit expense in all previous AFB administrative reviews. NTN argues that the only argument raised by Torrington, that reporting credit expense on an average basis may yield distortive results, is a statement applicable to dumping in general and is not specific to NTN's calculation of NTN's reported credit expense.

Department's Position: We agree with Torrington with regard to CEP sales. We have data on the record which allows us to calculate transaction-specific credit expense for CEP sales. Therefore, we have recalculated NTN's credit expense using the dates of payment which NTN reported. However, Torrington is incorrect in asserting that NTN reported transaction-specific payment dates for EP sales. NTN does not maintain its payment records in a manner which allows it to provide us with transaction-specific payment dates for EP sales to the United States (*see* NTN's September 9, 1996 submission at C–15). Therefore, in these reviews, as in past reviews, we are allowing NTN to calculate its U.S. credit expense for EP sales for each customer on the basis of the average number of days that receivables are outstanding. *See AFBs VI* at 201.

3.C. Indirect Selling Expenses

Comment 1: Torrington acknowledges that section 351.402(b) of the Department's new regulations directs the Department to deduct only those indirect expenses associated with sales to the unaffiliated customer in the United States and not those expenses which relate to the sale by the exporting company to the affiliated sales company in the United States. However, because SKF Germany has not provided adequate descriptions that would allow the Department to determine whether the expenses are associated with the sale to the affiliated company in the United States or with the subsequent resale to the unaffiliated U.S. customer, Torrington contends that the Department should deduct all indirect expenses incurred in Germany from CEP.

Torrington argues that, because Koyo attributed certain indirect selling expenses to its sales through its U.S. subsidiary, these expenses are related to sales to unaffiliated customers in the United States and the Department should deduct such expenses from CEP.

With regard to NSK, Torrington argues that the Department should deduct indirect selling expenses NSK incurred in Japan from CEP if they are associated with sales to the unaffiliated customer in the United States because NSK has not provided adequate descriptions which would allow the Department to determine with certainty whether indirect expenses incurred in Japan were associated with the sale to NSK's U.S. affiliate or with the subsequent resale to the unaffiliated U.S. customer. Citing NSK's chart of selling functions, Torrington asserts that it appears from the record that all of these expenses are related to U.S. resales, rather than sales to the U.S. affiliate, and argues that the Department should deduct all of these indirect expenses from CEP. Torrington argues that, at a minimum, the Department should regard the advertising component of NSK's indirect selling expenses incurred in Japan as associated with the resale to the unaffiliated U.S. customer and deduct the amount therefor from CEP.

Torrington argues that FAG has not demonstrated that certain expenses are associated with its sales to the U.S. affiliate rather than to the unaffiliated customers. Torrington contends that certain printing costs could be incurred in connection with sales to unaffiliated customers and, as such, the Department should deduct such expenses from CEP.

SKF Germany argues that the Department should not deduct these expenses from CEP because SKF Gleitlager and SKF GmbH incur the expenses with respect to their sales to SKF USA, not with respect to SKF USA's sales to the unaffiliated U.S. customer. SKF claims that the Department may only make such a deduction when these expenses are incurred in Germany with respect to sales in the United States to the unaffiliated customer.

Koyo states that Torrington has mischaracterized Koyo's commercial structure, which it states has remained unchanged from prior reviews. Koyo

further contends that the Department has verified that Koyo produces the subject merchandise and ships it to its U.S. affiliate, not the ultimate customer in the United States, and that its U.S. affiliate inventories the product and ultimately negotiates with and sells the merchandise to the unaffiliated U.S. customer. Thus, Koyo argues, its expenses attributable to U.S. sales are almost exclusively incurred in its transactions with its U.S. affiliate, not in that affiliate's transactions with the unaffiliated customers.

NSK argues that the indirect selling expenses to which Torrington refers were all associated with NSK's sales to its U.S. affiliate. NSK notes that Torrington asked the Department to request more information regarding these expenses in a supplemental questionnaire and asserts that, because the Department did not ask NSK any questions regarding these expenses, the Department must have been satisfied with NSK's explanation. With regard to advertising expenses, NSK asserts that this expense is general international advertising which the foreign parent incurred and is not related to NSK's sales to unaffiliated customers and, therefore, the Department should not make such a deduction from CEP.

FAG argues that there is nothing on the record to support Torrington's assertion that certain selling expenses could be incurred with regard to sales to unaffiliated customers. FAG argues that it reported these expenses properly for the following reasons: (1) They are exclusively related to the sales relationship between FAG Germany and FAG US; (2) they are not a direct advertising cost of FAG US incurred by FAG Germany; (3) they are in no way related to economic activity occurring in the United States and are therefore not deductible from CEP.

Department's Position: As we stated in *AFBs VI* at 2124, we will deduct only those expenses associated with economic activities in the United States which occurred with respect to sales to the unaffiliated U.S. customer. We found no information on the record for this review period to indicate that the indirect selling expenses SKF Germany, Koyo, NSK, or FAG incurred in their respective HMs were incurred on sales to the unaffiliated customer in the United States. Regarding NSK, the evidence on the record does not suggest that NSK incurred these expenses, including advertising expenses, on its U.S. affiliate's sales to unaffiliated customers in the United States. Rather, the U.S. affiliate does its own advertising in the United States which we have deducted from CEP as a direct expense. Furthermore, NSK has cooperated with all of our requests for information with regard to indirect selling expenses. Deducting these expenses from CEP on the basis of Torrington's speculation that there is a possibility that respondents may have incurred them on the U.S. affiliates' resales would be inappropriate. Therefore, because indirect selling expenses respondents incurred in the foreign countries were not related specifically to commercial activity in the United States, we did not deduct them from CEP.

Comment 2: FAG claims the Department treated certain other HM direct selling expenses improperly as indirect selling expenses. FAG argues that, while it incurs an indirect expense regardless of whether a particular sale takes place, the other expenses were related directly to the distributor's sale of a particular bearing to an unrelated original equipment manufacturer (OEM) at the behest of FAG. FAG asserts that it explained in its questionnaire response that the direct credit to this distributor is functionally equivalent to a commission because it is a payment to the distributor on account of its sale to FAG's OEM customer. FAG contends that the Department should not consider this expense as an indirect selling expense since it incurred the expense with respect to a particular customer. Furthermore, FAG claims that allocation of a direct expense on a customer-specific basis is reasonable and proper when transaction-specific reporting is not possible, citing the SAA at 823–824.

Torrington counters that the selling expenses under contention should not be classified as direct selling expenses as FAG requests because FAG has not demonstrated how these are tied to a specific transaction. Torrington points out that the Department requested information from FAG which could demonstrate how the distributor's sale to its customer was tied directly to FAG's sale to the distributor and that FAG answered that there was no direct tie between the two sales. Since FAG did not link these payments directly to sales it made to the distributor, Torrington asks that the Department continue to treat these payments as indirect expenses.

Department's Position: We disagree with FAG. As Torrington observes, we asked FAG in a supplemental questionnaire ''[i]f there is a direct * * * tie between your sales and the customer's sales for which this expense is incurred, please explain the tie and submit documentary evidence to support your claim,'' to which FAG responded ''[t]here is no direct tie between FAG's reported sales to the distributor and the sales of the distributor that generate the payment or credit.'' *See* FAG KGS Section A–D Supplemental Response dated December 10, 1996 at 30. FAG acknowledges in its case brief that this expense is ''directly related to the distributor's sale of a particular bearing to an unrelated OEM at the behest of FAG.'' *See* FAG's German Case Brief dated June 30, 1997. Because the expense is related directly to the distributor's sale, FAG would have to demonstrate that there is a direct tie between its sales to the distributor and the distributor's sale that generates the payment for us to regard this as a direct expense. As noted above, FAG did not demonstrate such a tie.

FAG argues that this expense is functionally equivalent to a commission. We note, however, that ''[g]enerally speaking, a commission is a payment to a sales representative for engaging in sales activity, normally on behalf of the seller but occasionally on behalf of the customer'' and that ''the key question * * * is whether there was one transaction between [the respondent] and the ultimate purchaser in which the trading companies acted as [the respondent's] sales representatives for a commission '' or '' whether there were two transactions, one in which the trading companies bought from [the respondent] and received a [payment or credit] for that initial sale and the ultimate purchaser then bought from the trading companies.'' *See Certain Cold-Rolled Carbon Steel Flat Products From Germany; Final Results of Antidumping Duty Administrative Review,* 60 FR 65264 at 65278. In the instant situation, there are two transactions, one from FAG to the distributor and one from the distributor to the downstream customer (*e.g.,* sales to the unaffiliated third party). Thus, these expenses cannot be considered a commission. Finally, we note that FAG did not demonstrate that these payments were contemplated at the time of sale to the distributor. Therefore, because this expense is related to a downstream sale and not to the sales which FAG reported, this expense is an indirect selling expense, not a direct selling expense or a commission.

Finally, we did not treat these selling expenses as indirect because they were allocated on a customer-specific basis. Had we concluded that the expense was direct in nature but that FAG had failed to report it to the best of its ability or that its allocation was unreasonable, we would have denied the adjustment entirely. The fact that FAG allocated this expense did not enter into our

decision to treat it as an indirect expense. As stated above, we treated these selling expenses as indirect expenses because FAG did not demonstrate that there is a direct tie between its sales to the distributor and the distributor's sale that generates the payment.

Comment 3: Torrington contends that NTN excluded certain expenses improperly from the category of reported U.S. indirect selling expenses and states that, for the purpose of the final results, the Department should deduct these expenses from CEP.

NTN argues that the Department has rejected Torrington's claim previously that the expenses to which Torrington refers were excluded from the category of reported U.S. indirect selling expenses improperly. NTN points out that, in the 1994/95 administrative reviews, the Department found that NTN's reporting of such expenses was not unreasonably distortive. NTN asserts that it has used the same methodology to report this category of expenses in the current reviews and, therefore, Torrington's argument is baseless.

Department Position: We agree with NTN. Having verified these expenses in past reviews and found the adjustments to be reasonable, we accepted them in the 1994/95 administrative reviews. *See AFBs VI* at 2105. For these reviews, after examining the record, we asked supplemental questions which NTN answered appropriately. Inasmuch as the record in these reviews indicates no reason that a different methodology should be used, we have accepted NTN's adjustments to its reported U.S. indirect selling expenses.

Comment 4: NTN Japan contends that the Department should recalculate NTN Japan's U.S. selling expenses to reflect its reported indirect-selling-expenses level-of-trade allocations. NTN Japan argues that the Department intended to calculate NTN Japan's U.S. selling expenses based on the reported levels of trade but did not do so in its preliminary calculations. NTN Japan maintains further that, in the 1992/93 TRB administrative review in which NTN Japan was involved, the Department accepted NTN Japan's level-of-trade-based U.S. selling expenses because it concluded that it prevents distortions.

Torrington contends that the Department should reject NTN Japan's reported selling expense allocations based on level of trade. Torrington states that, for the preliminary results, the Department recalculated NTN Japan's U.S. selling expenses without regard to level of trade correctly. Torrington states further that, in *AFBs VI*, the Department rejected NTN Japan's allocation methodology because it was distortive and unsubstantiated. Finally, Torrington states that NTN Japan's cite to the TRB case is misplaced because, in that case, the Department recalculated NTN Japan's U.S. selling expense allocations based on level of trade as a result of other problems inherent in NTN Japan's response.

Department's Position: We agree with Torrington. In *AFBs III* (and subsequently in *AFBs IV* at 10940, *AFBs V* at 66489, and *AFBs VI* at 2105), we determined that NTN Japan's indirect-selling-expense allocation methodology based on levels of trade bears no relationship to the manner in which it actually incurs these U.S. selling expenses, which ultimately results in distorted allocations. The CIT upheld this decision in *NTN Bearing Corp. v. United States*, 905 F. Supp. 1083 at 1094–95 (1995)*(NTN III)*. NTN Japan did not provide record evidence to substantiate its claim that its indirect selling expenses are attributable to and vary by its reported levels of trade. Therefore, for these final results, we have maintained the recalculation of NTN Japan's U.S. indirect selling expenses we made for the preliminary results to represent such selling expenses for all U.S. sales.

4. Level of Trade

As set forth in section 773(a)(7) of the Tariff Act and in the SAA at 829–831, to the extent practicable, we have determined NV based on sales at the same level of trade as the level of trade of the EP or CEP. When we were unable to find comparison sales at the same level of trade as the EP or CEP, we compared the U.S. sales to sales at a different level of trade in the comparison market.

We determined the level of trade of EP on the basis of the starting prices of sales to the United States. We based the level of trade of CEP on the price in the United States after making the CEP deductions under section 772(d) but before making the deductions under section 772(c). Where HM prices served as the basis for NV, we determined the NV level of trade based on starting prices in the NV market. Where NV was based on constructed value (CV), we determined the NV level of trade based on the level of trade of the sales from which we derived selling, general and administrative expenses (SG&A) and profit for CV.

In order to determine the level of trade of U.S. sales and comparison sales, we reviewed and compared distribution systems, including selling functions, class of customer, and the extent and level of selling expenses for each claimed level of trade. Customer categories such as distributor, original equipment manufacturer (OEM), or wholesaler are commonly used by respondents to describe levels of trade but are insufficient to establish a level of trade. Different levels of trade necessarily involve differences in selling functions, but differences in selling functions, even substantial ones, are not alone sufficient to establish a difference in the levels of trade. Different levels of trade are characterized by purchasers at different stages in the chain of distribution and sellers performing qualitatively or quantitatively different functions in selling to them. *See AFBs VI* at 2105.

As in the preliminary results, where we established that the comparison sales were made at a different level of trade than the sales to the United States, we made a level-of-trade adjustment if we were able to determine that the differences in levels of trade affected price comparability. We determined the effect on price comparability by examining sales at different levels of trade in the comparison market. Any price effect must be manifested in a pattern of consistent price differences between foreign market sales used for comparison and foreign market sales at the level of trade of the export transaction. To quantify the price differences, we calculated the difference in the average of the net prices of the same models sold at different levels of trade. We used the average difference in net prices to adjust NV when NV is based on a level of trade different from that of the export sale. If there was a pattern of no price differences, the differences in levels of trade did not have a price effect and, therefore, no adjustment was necessary.

We were able to quantify such price differences and make a level-of-trade adjustment for certain comparisons involving EP sales, in accordance with section 773(a)(7)(A). For such sales, the same level of trade as that of the U.S. sales existed in the comparison market but we could only match the U.S. sale to comparison-market sales at a different level of trade because there were no usable sales of the foreign like product at the same level of trade. Therefore, we determined whether there was a pattern of consistent price differences between these different levels of trade in the HM. We made this determination by comparing, for each model sold at both levels, the average net price of sales made in the ordinary course of trade at the two levels of trade. If the average prices were higher at one of the levels

of trade for a preponderance of the models, we considered this to demonstrate a pattern of consistent price differences. We also considered whether the average prices were higher at one of the levels of trade for a preponderance of sales, based on the quantities of each model sold, in making this determination. We applied the average percentage difference to the adjusted NV as the level-of-trade adjustment.

We were unable to quantify price differences in other instances involving comparisons of sales made at different levels of trade. First, with respect to CEP sales, the same level of trade as that of the CEP for merchandise under review did not exist in the comparison market for any respondent except NMB/Pelmec. We also did not find the same level of trade in the comparison market for some EP sales of merchandise under review. Therefore, for comparisons involving these sales, we could not determine whether there was a pattern of consistent price differences between the levels of trade based on respondents' HM sales of merchandise under review.

In such cases, we looked to alternative sources of information in accordance with the SAA. The SAA provides that ''if information on the same product and company is not available, the level-of-trade adjustment may also be based on sales of other products by the same company. In the absence of any sales, including those in recent time periods, to different levels of trade by the exporter or producer under investigation, Commerce may further consider the selling expenses of other producers in the foreign market for the same product or other products.'' *See* SAA at 830. Accordingly, where necessary, we attempted to examine the alternative methods for calculating a level-of-trade adjustment. In these reviews, however, we did not have information that would allow us to apply these alternative methods for companies that, unlike NMB/Pelmec, did not have a HM level of trade equivalent to the level of the CEP.

The only company for which we made a level-of-trade adjustment for CEP sales in these final results was NMB/Pelmec. *See* the discussion at Comment 7, below. However, we concluded that it would be inappropriate to apply the level-of-trade adjustment we calculated for NMB/Pelmec to any of the other respondents. The SAA at 160 states that ''if information on the same product and company is not available, the adjustment may also be based on sales of other products by the same company. In the absence of any sales, including those in recent time periods, to different levels of trade by the exporter or producer under investigation, Commerce may consider the selling experience of other producers in the foreign market for the same product in other products.'' Because no respondent reported sales in the same market as NMB/Pelmec (*i.e.*, Singapore), we have not used NMB/Pelmec's data as the basis of a level-of-trade adjustment for any other respondents.

In those situations where the U.S. sales were EP sales and we were unable to quantify a level-of-trade adjustment based on a pattern of consistent price differences, the statute requires no further adjustments. However, with respect to CEP sales for which we were unable to quantify a level-of-trade adjustment, we granted a CEP offset where the HM sales were at a more advanced level of trade than the sales to the United States, in accordance with section 773(a)(7)(B) of the Tariff Act.

Comment 1: Koyo, NMB/Pelmec, NTN Germany, SNR France, NSK, and NSK/RHP contend that the Department's practice with regard to level of trade effectively precludes a level-of-trade adjustment to NV for CEP sales and is thus contrary to law and Congressional intent.

NMB, NSK, and NSK/RHP contend that there is no statutory requirement that a level-of-trade adjustment be based on the full difference in prices between the HM comparison level of trade and the HM level of trade equivalent to CEP and suggest that a partial level-of-trade adjustment is contemplated by the statute. NMB/Pelmec argues that neither the URAA nor the SAA specifies which two levels of trade must be the basis for the adjustment. NSK and NSK/RHP contend that the plain reading of the statute requires that the Department must adjust NV for CEP sales for the difference between price levels at the two levels of trade which do exist in the HM. NSK and NSK/RHP argue further that the Department should at least make such a level-of-trade adjustment when comparing CEP to HM aftermarket (AM) sales which, they contend, is more advanced than HM OEM sales because prices are higher at the HM AM level of trade than at the HM OEM level of trade. Finally, NSK and NSK/RHP contend that CEP sales should be matched to HM OEM sales before they are matched to HM AM sales.

Koyo asserts that it and other respondents have proposed to the Department alternative methods by which the Department could construct an appropriate HM level of trade by deducting from NV those HM expenses that correspond to the expenses that are deducted from CEP, but that the Department has failed to provide a reasonable explanation for rejecting the proposals.

SNR France contends that its claim for a level-of-trade adjustment is based on information on the record that demonstrates a consistent pattern of price differences between OEM and distributor customers. Moreover, SNR France claims that its OEM sales are made at a level similar to the CEP level of trade. It suggests that if the CEP and OEM level of trade were identical (*i.e.*, if selling functions and activities performed were the same) price differences between OEM and distributor customers would be even greater. Thus, SNR France asserts, its claimed adjustment is understated and it is entitled to this conservative adjustment when CEP sales are compared to HM sales at the distributor level of trade.

Torrington contends that an analysis of patterns of consistent price differences between sales at different levels of trade in the HM cannot be performed absent a HM level of trade equivalent to the level of trade of the U.S. sale. Torrington also argues that the Department's requirement that price differences be due to HM level-of-trade differences before price-based adjustments are allowed is logical since many factors, not all of which pertain to level of trade, determine price. Torrington contends further that the balance achieved by the Department in selecting the appropriate sales to compare in the two markets on the basis of level of trade would be disturbed if the Department allowed a level-of-trade adjustment to eliminate a whole set of price determinants in one market while not removing them in the other market. Thus, Torrington concludes, the respondents' suggested level-of-trade adjustment would result in unfair comparisons. Finally, Torrington argues that Koyo's position concerning alternative methods is without supporting authority.

Department's Position: We disagree with respondents. Our methodology does not preclude level-of-trade adjustments to NV for CEP sales; we made such an adjustment in the case of NMB/Pelmec. Rather, we did not make a level-of-trade adjustment to NV for CEP sales where the facts of the case did not warrant such an adjustment.

Based upon our examination of the information on the record, with the exception of NMB/Pelmec, we found that no respondent in these reviews had a HM level equivalent to the level of the CEP. Furthermore, we find no provision in the statute for making a ''partial''

level-of-trade adjustment. We may make level-of-trade adjustments when there is ''any difference * * * between the export price or constructed export price and the [NV] that is shown to be wholly or partly due to a difference in level of trade between the export price or constructed export price and the normal value.'' *See* section 773(a)(7)(A) of the statute. While respondents seize on the phrase ''wholly or partly'' to justify a partial level-of-trade adjustment, we interpret this phrase to mean that we may make a level-of-trade adjustment if only part of the differences in prices between two levels of trade is attributable to a difference in levels of trade. In other words, we need not demonstrate that no factor other than level of trade influenced a pattern of price differences. Thus, we do not read into this language of the statute the authority to make a level-of-trade adjustment between two HM levels of trade where neither level is equivalent to the level of the U.S. sale.

With regard to SNR's claim that its OEM sales are made at a level of trade similar to the CEP level of trade and that SNR should be granted a level-of-trade adjustment when comparing CEP sales to distributor sales, we found that all of SNR's HM sales are made at a different level of trade than the level of the CEP. Therefore, for the reasons enumerated above, it is inappropriate to grant a level-of-trade adjustment to SNR for its CEP sales.

We disagree with Koyo that we should adopt proposed alternative methods by which to construct HM levels of trade. We base HM levels of trade on the respondent's actual experience in selling in the HM. There is no statutory basis for us to ''construct'' levels in the HM or elsewhere. Therefore, we have not used Koyo's claimed constructed NV levels of trade in order to calculate a level-of-trade adjustment for Koyo's CEP-sales comparisons.

Finally, we disagree with NSK and NSK/RHP that these companies' CEP sales should be matched to HM OEM sales before they are matched to HM AM sales. Based upon our examination of the information on the record, we found that no HM level of trade for either NSK or NSK/RHP had conclusively more selling functions than another HM level. Rather, the HM levels of trade each involved different degrees of various selling functions. We conclude that, for these companies, and for respondents generally, while the reported HM levels of trade are different from one another, no HM level of trade is more advanced than any other based upon the evidence on the record. We also disagree with NSK's and NSK/RHP's assertion that, because their OEM prices are generally lower than their AM prices, their OEM levels of trade is less advanced than the distributor/aftermarket levels of trade. We determine whether one level of trade is more advanced than another on the basis of the selling functions performed by a respondent with respect to the two levels of trade. NSK and NSK/RHP's HM OEM and AM sales are more advanced than the level of trade of the CEP because comparatively fewer selling functions are associated with the CEP than are performed for sales to either of the other levels of trade. Therefore, we have not altered our matching methodology.

Comment 2: Torrington contends that SKF Germany and SKF Sweden did not provide adequate information to support their claims for a CEP offset and requests that the Department deny this adjustment. Torrington asserts that respondents' explanation of differences in selling functions between the CEP level of trade and the two HM levels do not support an offset because an examination of these selling functions reveals that they are either duplicative, *de minimis*, equally applicable to sales to U.S. affiliate and HM sales, or the Department adjusts for them otherwise. Torrington concludes that the information respondents provided regarding differences in selling activities is insufficient for the Department to determine whether respondents' CEP is less remote than the level of trade of HM OEM sales.

SKF Germany and SKF Sweden assert that the Department determined correctly that they are entitled to a CEP offset based on differences in selling activities and functions between the HM levels of trade and the CEP level of trade. Respondents contend that they substantiated their CEP-offset claims fully in submissions to the Department, including the differences in selling functions between HM levels of trade and the CEP level of trade. SKF Germany contends further that these claimed differences are ''identical in all material respects'' to the information the Department verified in the 1994/95 reviews. SKF Sweden notes that during the current segment of these proceedings the Department verified the information it provided concerning selling activities and functions for each level of trade. Respondents assert that the preliminary results are in accordance with section 773(a)(7)(B) of the Tariff Act and entirely supported by the record. On this basis, respondents request that the Department reject Torrington's arguments and continue to grant the CEP offset in the final results.

Department's Position: We disagree with Torrington and determine that respondents provided adequate factual information to support their claims that the HM levels of trade are in fact more advanced than the CEP level of trade. It appears that Torrington may have misinterpreted the data presented in respondents' submissions. We conducted a thorough analysis of the information SKF Sweden and SKF Germany submitted on the record and determined that after deducting respondents' expenses from CEP pursuant to section 772(d) there exists adequate factual information to conclude that fewer selling functions are associated with the CEP than are performed on sales at their HM levels of trade. Thus, for both respondents, we considered the CEP level of trade to be different from either HM level of trade and a less advanced stage of distribution. *See* Memorandum to Laurie Parkhill, Level of Trade, March 24, 1997, in Import Administration's Central Records Unit (Room B–099 of the main Commerce building (hereafter, B–099)).

For the final results, because we could neither match the CEP level of trade to sales at the same level of trade in the HM nor determine a level-of-trade adjustment based on these respondents' HM sales, to the extent possible we determined NV at the same level of trade as the U.S. sale to the unaffiliated customer and made a CEP offset in accordance with section 773(a)(7)(B) of the Tariff Act (*see AFBs VI* at 2105).

Comment 3: Torrington claims that the Department's pattern-of-prices analysis does not support a downward level-of-trade adjustment to NV for differences between SKF France's EP sales matched to HM sales at the distributor level of trade.

SKF France disagrees with Torrington, arguing that the Department's adjustment methodology is correct. SKF France asserts that a clerical error in the Department's analysis memorandum, which reverses the relative price levels of the two HM levels, misled Torrington into thinking that the downward adjustment is inappropriate. SKF France cites to the results of the Department's level-of-trade adjustment calculations to support that a downward adjustment to NV is appropriate when matching its EP sales to HM sales at the distributor level.

Department's Position: We disagree with Torrington. We did not err in making a downward level-of-trade adjustment for SKF France's EP sales which we matched to HM distributor sales. Torrington's contentions are based upon a typographical error in the SKF

France preliminary results analysis memorandum which reversed the price levels of the HM levels of trade. Therefore, respondent's downward level-of-trade adjustment was proper.

Comment 4: NTN Japan and NTN Germany state that the Department should make a price-based level-of-trade adjustment for CEP sales made at a different level of trade in the United States than the comparison home market sales. Respondents suggest that using the transaction to the first unaffiliated U.S. customer prior to the deduction of expenses pursuant to section 772(d) would be consistent with the use of those levels of trade in matching U.S. CEP and HM sales and with evidence demonstrating that different selling activities are performed at each level of trade that affect price comparability.

Torrington argues that the Department's requirement that price differences be due to HM level-of-trade differences before price-based adjustments are allowed is logical since many factors, not all of which pertain to level of trade, determine price.

Department's Position: We disagree with NTN Japan and NTN Germany. The statutory definition of ''constructed export price'' contained at section 772(d) of the Tariff Act indicates clearly that we are to base CEP on the U.S. resale price, as adjusted for U.S. selling expenses and profit. As such, the CEP reflects a price exclusive of all selling expenses and profit associated with economic activities occurring in the United States. *See* SAA at 823. These adjustments are necessary in order to arrive at, as the term CEP makes clear, a ''constructed'' EP. The adjustments we make to the starting price, specifically those made pursuant to section 772(d) of the Tariff Act (''Additional Adjustments for Constructed Export Price''), normally change the level of trade. Accordingly, we must determine the level of trade of CEP sales exclusive of the expenses (and associated selling functions) that we deduct pursuant to this sub-section. With regard to respondents' characterization of our matching methodology, we generally matched CEP sales to HM sales on the basis of the level of trade of the resale by the U.S. affiliate *only* where all HM levels of trade were more remote than the level of the CEP. The purpose of this methodology is to use the CEP offset to deduct indirect selling expenses from NV similar to those deducted from the U.S. starting price. For example, we were able to determine the CEP offset ''cap'' for HM OEM sales on the basis of indirect selling expenses incurred on OEM sales in the United States. Therefore, because no HM levels of trade reported by NTN Germany or NTN Japan were equivalent to the level of trade of these respondents' CEP sales, we were unable to make a level-of-trade adjustment for such sales.

Comment 5: Torrington argues that the record does not support NSK/RHP's claim for a CEP offset. Torrington contends that the Department improperly found that several selling functions associated with the CEP level of trade are substantially different from the sales functions associated with the comparison sales in the HM. For instance, Torrington states that the Department claimed erroneously that, at the CEP level of trade, little or no advertising was involved. Torrington states further that the Department determined incorrectly that certain selling functions (*e.g.*, technical support and strategic and economic planning) did not apply to the CEP level of trade. With respect to repacking expenses, Torrington contends that this function is not involved in the selling process and therefore should not justify a CEP offset. Citing *Certain Corrosion Resistant Carbon Steel Flat Products*, 62 FR 18,452 (April 15, 1997), Torrington argues that differences in selling functions, even substantial ones, may not be enough to warrant finding different levels of trade. Torrington suggests that the Department continue to compare prices within the broad comparison patterns but reject NSK/RHP's claim for a CEP offset based on these reasons.

NSK/RHP asserts that Torrington compares incorrectly the activities in which an international distributor engages when selling to a U.S. national distributor with activities of a U.K. national distributor selling to customers. Moreover, NSK/RHP contends that, after the initial error, Torrington then compares a category of expense (*e.g.*, advertising) at different points in the chain of distribution and suggests that the same function is performed by each national distributor. NSK/RHP contends further that, for CEP sales, it did not report advertising for its end-user customers because the Department deducts expenses for the function of advertising to unaffiliated U.S. customers in the calculation of CEP pursuant to section 772(d) of the Tariff Act. NSK/RHP notes that it agrees with Torrington that repacking is not a selling expense within the scope of section 772(d) of the statute. NSK/RHP therefore suggests that the Department remove repacking from the CEP-selling-function variable in the final results. NSK/RHP asserts that the Department should follow the statute as written and grant a level-of-trade adjustment for CEP matches or, at a minimum, grant a level-of-trade adjustment for CEP sales matched to HM aftermarket sales.

Department's Position: We disagree with Torrington. Torrington compares erroneously activities of an international distributor when selling to a U.S. affiliate with activities of a U.K. national distributor selling to customers. As we stated in our March 24, 1997 Memorandum (*Id.*), we could not determine whether these sales (*i.e.*, sales from the international distributor to the U.K. national distributor) were made at arm's length. Therefore, we did not use these sales to determine NV or as the basis of any level-of-trade adjustments. As a result of this determination, we compared sales made by the U.K. national distributor to customers in the HM with sales made at the CEP level of trade (*i.e.*, sales made by the international distributor to the U.S. affiliate). *See* NSK/RHP's February 6, 1997, supplemental questionnaire response (Exhibit S–2). Based on our analysis, we found that, for CEP sales, NSK/RHP did not engage in any of these selling activities (*e.g.*, freight and delivery arrangement, inventory maintenance, repacking, pre-sale warehousing and sales calls). However, we found that, at the HM levels of trade, NSK/RHP participated in these activities and therefore the HM levels of trade were substantially dissimilar from the CEP level of trade. Accordingly, as we explain in our level-of-trade memorandum, we considered the HM sales to be at different levels of trade and at a more advanced stage of distribution than CEP.

We agree with Torrington that differences in selling functions may not be enough in themselves to warrant finding different levels of trade. However, consistent with our practice in *AFB VI*, we consider the class of customer as one factor, along with selling functions and the selling expenses associated with these functions, in determining the stage of marketing, *i.e.*, the level of trade associated with the sales in question. *See AFB VI* at 2107.

With respect to expenses associated with repacking, please see our discussion in comment 1 of section 7 of this notice for an explanation of our treatment of repacking expenses.

Comment 6: Torrington argues, with respect to Barden's HM sales to government users, that the Department should not have determined that government users are at a different level of trade than OEM sales. Torrington asserts that there is no evidence on the record to support Barden's claim that

government sales should be treated separately. In addition, Torrington contends that Barden's assertion that AM sales to airlines and repair contractors should be treated separately is also unsupported. Torrington states that Barden has not submitted adequate evidence to support its claim that AM sales should be treated separately from distributor sales. Moreover, Torrington claims that Barden's narrative explanations for certain selling functions (*e.g.*, computer, legal and accounting, personnel training, advertising, and strategic and economic planning) do not support the level-of-trade chart found in Exhibit A–4 of Barden's July 23, 1996, Section A Response. Therefore, according to Torrington, the Department should treat AM sales as being at the same level as distributor sales.

Barden states that it agrees with Torrington that the Department's redesignation of its HM level-of-trade categories was in error. Barden contends that neither the record nor commercial reality supports the inclusion of these two very distinct and separate channels of distribution (airline and repair AM contractors and government customers) under one level of trade. Therefore, according to Barden, the Department should use the customer category designations Barden submitted originally in its responses for these final results. Barden also contends that the Department should designate sales to its EP customers (*e.g.*, network distribution customers) as Barden originally identified on the record. Barden asserts that the Department unlawfully applied a facts-available level-of-trade adjustment to these sales because Barden allegedly failed to include them in their proper channels of distribution. Barden contends that it disclosed the types of selling activities and functions it incurred on its EP sales fully in its response to the Department's questionnaire.

Department's Position: We disagree with Torrington and Barden. While we acknowledge that Barden did not provide sufficient evidence to warrant a distinction for government sales, we disagree with Torrington that we should treat these sales as OEM sales. Torrington has provided no evidence nor any references to information on the record that supports its conclusion. Moreover, there is no evidence on the record that would suggest that government sales are similar to OEM sales. In addition, with respect to Barden's assertion that government sales differ substantially from any of the other level-of-trade categories, we determined that Barden's narrative explanation does not provide sufficient information to support its conclusion. Therefore, we have not changed our analysis from that in our preliminary results with respect to this issue.

We also disagree with Torrington's contention that we should treat AM sales as being at the same level as distributor sales. As we explained in our March 24, 1997 Memorandum (*Id.*), we found that the selling activities for level two (*e.g.*, distributors network) differed from those of level three (*e.g.*, airlines repair contractors (AM sales) and government customers) in after-sales services and warranties, advertising, administrative support and personnel training. While we agree with Torrington's assertion that there are certain discrepancies between Barden's narrative explanations and its level-of-trade chart, we have determined that such inconsistencies were not substantial. Thus, we have not made any changes with respect to this issue.

Finally, we have reexamined our facts-available determination with respect to Barden's EP sales. Upon further consideration, we determined that Barden did provide sufficient information concerning the nature of its customers and the selling functions it performed with respect to these sales. Therefore, we have accepted Barden's information and have not applied facts available to these sales for the final results.

Comment 7: Torrington claims that NMB/Pelmec failed to demonstrate entitlement to either a level-of-trade adjustment or a CEP offset to its HM prices and that the Department should not make either adjustment to NV in the final results.

Torrington notes that, in the preliminary results for NMB/Pelmec, the Department adjusted NV downward in the amount of the CEP offset. Torrington also notes that NMB admits that its distributor sales in the HM are at the same level of trade as the CEP level of trade in the United States. Torrington concludes that, because NMB/Pelmec reported no distributor sales in the HM during the POR, NMB is entitled to an adjustment in the form of a CEP offset only if it demonstrated that OEM sales in the HM were at a more advanced level of trade than the CEP level of trade. Torrington argues that this is not the case. It notes that NMB/Pelmec admits that selling expenses, such as after-sales service/warranties, technical advice and engineering services, and direct advertising, were all negligible or non-existent and, therefore, NMB/Pelmec omitted them from the computer-database fields. Torrington continues that, because these expenses were not reported, NMB/Pelmec made no visits to customers for these functions. Therefore, Torrington argues, these functions do not support NMB/Pelmec's claim for a CEP offset. Torrington notes further that indirect expenses with regard to solicitation of customer orders were also admittedly negligible. Thus, Torrington argues, there is no other information on the record to support NMB/Pelmec's claim that this function is more active in the case of sales to OEM customers.

Finally, Torrington alleges that NMB/Pelmec reports substantial activity at the CEP level of trade, which, at a minimum, undermines NMB/Pelmec's claim that a downward adjustment to NV is needed when comparison sales are to OEMs. Torrington points to a description in NMB/Pelmec's financial report of its U.S. affiliate as evidence.

NMB/Pelmec claims that Torrington's characterizations of its sales are incorrect. It argues that the Department should find that NMB/Pelmec is entitled to a level-of-trade adjustment and, at a minimum, a CEP offset whenever CEP sales are not compared to HM distributor sales. NMB/Pelmec contends that Torrington's claim that it did not report any distributor sales in the HM during the period is incorrect. NMB/Pelmec notes that the Department's preliminary findings that NMB/Pelmec did not report such sales were also incorrect. NMB/Pelmec points out that the record in this administrative review demonstrates clearly that it made substantial sales to distributors. Thus, NMB/Pelmec argues that the Department should have compared CEP sales to HM distributor sales. NMB/Pelmec asks that the Department correct its findings in the final results.

In addition, NMB/Pelmec contests Torrington's argument that NMB/Pelmec has not demonstrated that its HM OEM sales were at a more advanced level than the CEP level of trade. NMB/Pelmec replies that it provided detailed descriptions of selling functions for HM OEMs in its initial and supplemental responses, explaining that most of these functions were not performed for distributors, in addition to providing detailed sample support documentation. NMB/Pelmec states that, during the Department's verification of the 1994/95 administrative review, the Department verified NMB/Pelmec's claim that it performed more advanced selling functions for OEMs. NMB/Pelmec alleges that Torrington's claim appears to be based on confusion regarding the difference between direct and indirect selling expenses and on its failure to review the correction regarding selling

functions NMB/Pelmec made in its supplemental response. NMB/Pelmec contends that Torrington ignored the supplemental corrections and based its claims on obvious errors.

Finally, NMB/Pelmec argues that Torrington failed to support its claim that NMB/Pelmec reported substantial activity at the CEP level of trade. It notes that the activities to which Torrington refers in NMB/Pelmec's consolidated financial statement were between NMB/Pelmec's parent company and its U.S. affiliate, not between NMB/Pelmec and its U.S. affiliate. Thus, NMB/Pelmec concludes, these activities do not support Torrington's claim. NMB/Pelmec also notes that the record shows that its parent company provides the same types of activities to its other subsidiaries and affiliates.

Department's Position: NMB/Pelmec reported distributor sales for the POR. We stated incorrectly in our analysis memorandum for NMB/Pelmec that it only made sales to OEM/trading companies during the period. This statement was a result of our mis-coding the customer categories NMB/Pelmec reported when applying our methodology for identifying the proper level of trade. We have now made the appropriate changes to calculate NMB/Pelmec's margins properly for these final results.

We agree with NMB/Pelmec that it is entitled to a level-of-trade adjustment whenever CEP sales are not compared to HM distributor sales. We re-examined NMB/Pelmec's response and determined that NMB/Pelmec's HM distributor sales are equivalent to the CEP level of trade. The evidence on the record suggests, contrary to Torrington's assertion, that NMB/Pelmec performs comparatively few selling activities either for sales to its U.S. affiliate or for HM sales to distributors. Furthermore, we determined that NMB/Pelmec's HM sales to OEMs are made at the same level of trade as its HM sales to trading companies but that these sales are made at a different level of trade than its HM distributor sales. Accordingly, we attempted to match CEP sales to HM distributor sales first and we matched CEP sales to OEM/trading company sales when no HM distributor sales existed. When we matched CEP sales to HM distributor sales, we made no level-of-trade adjustment or CEP offset because the sales are made at the same level of trade. When we matched CEP sales to HM OEM/trading company sales, we made a level-of-trade adjustment because we found that there was a pattern of consistent price differences between the two HM levels of trade. *See* NMB/Pelmec Final Results Analysis Memorandum dated September 22, 1997.

Finally, because we made a level-of-trade adjustment for comparisons involving HM OEM/trading company sales, we did not make a CEP offset for any comparisons of NMB/Pelmec's sales.

Comment 8: Torrington contends that NTN failed to provide record evidence demonstrating its entitlement to either a level-of-trade adjustment to NV for CEP sales or a CEP offset for those sales. With respect to NTN's identification of comparative selling activities, Torrington argues that, primarily, NTN identifies selling activities associated with CEP-resale transactions and states that NTN failed to provide a complete and accurate list of selling activities. In addition, Torrington contends that NTN did not provide a comprehensive description of its distribution and selling processes. Torrington also maintains that the quantification information that NTN provided in its response lacks the necessary detail to support a level-of-trade adjustment. Torrington concludes that, for the purpose of the final results, the Department should not grant NTN either a level-of-trade adjustment or a CEP offset to NV.

NTN contends that Torrington misreads the Department's questions and misinterprets NTN's data. NTN argues that, in its response, it identified distinct selling functions related to the different LOTs in the United States for both EP and CEP sales. NTN maintains that it provided responses to the Department's requests for information related to the selling functions and sales processes performed for, and the services offered to, each class of customer in both the United States and HM. NTN argues that it based its responses to the Department's level-of-trade and channel-of-distribution inquiries on its responses in the 1994/95 administrative reviews and states that, in those reviews, the Department accepted NTN Japan's responses.

Department's Position: We disagree with Torrington. NTN Japan provided adequate factual information to support its claims that its HM levels of trade are in fact more remote than the CEP level of trade. We conducted a thorough analysis of the information NTN Japan submitted on the record and determined that after deducting NTN Japan's expenses from CEP pursuant to section 772(d) there exists adequate factual information to conclude that fewer selling functions are associated with the CEP than are performed on sales at its HM levels of trade. Thus, for NTN Japan we considered the CEP level of trade different from all HM levels of trade and at a less-advanced stage of distribution.

For the final results, because we could neither match the CEP level of trade to sales at the same level of trade in the HM nor determine a level-of-trade adjustment based on NTN's HM sales, to the extent possible we determined NV at the same level of trade as the U.S. sale to the unaffiliated customer and made a CEP offset in accordance with section 773(a)(7)(B) of the Tariff Act. *See* our position in response to comment 4, above.

Comment 9: Torrington contends that, with respect to the customers to which NTN made EP sales, the Department should not make a level-of-trade adjustment to NV based on the record evidence developed in the instant reviews. Torrington asserts that the record contains little information pertaining to such sales. In addition, Torrington argues that the information that is on the record is inadequate to warrant a level-of-trade adjustment.

NTN argues that it has not changed the facts related to these sales from those of the 1994/95 administrative reviews and states that, in those reviews, the Department made a level-of-trade adjustment for such sales. NTN also points out that the Department verified, in detail, NTN's response as it relates to its claimed levels of trade and found no discrepancies. NTN asserts that, because the Department made no further requests for information, the Department has, in essence, accepted NTN's responses as sufficient to warrant a level-of-trade adjustment with respect to EP sales it made to both customers.

Department Position: We disagree with Torrington. NTN Japan provided adequate factual information to support its claims with regard to the differences and similarities of its HM levels of trade and the EP level of trade. Therefore, where possible, we matched EP sales to sales at the same level of trade in the HM and made no level-of-trade adjustment. Where we matched EP sales to HM sales made at a different level of trade, in accordance with section 773(a)(7)(A) of the Tariff Act, we first determined whether there was a pattern of consistent price differences between these different levels of trade in the HM and, if so, made a level-of-trade adjustment accordingly.

5. Cost of Production and Constructed Value

5.A. Cost-Test Methodology

Comment 1: INA claims that the Department used CV for NV rather than seeking to make a family-match comparison where identical HM

matches existed but were disregarded because they were below cost. INA contends that this approach is in error because it gives priority to the use of CV over price-based NV. Citing section 773(a)(4) of the Tariff Act, INA contends that the Department is to use CV only when it determines that the NV of the merchandise cannot be determined by comparison with sales of the foreign like product. INA asserts further that section 773(b)(1) reinforces this conclusion by stating that, when below-cost sales are disregarded, ''normal value shall be based on the remaining sales of the foreign like product in the ordinary course of trade. If no sales made in the ordinary course of trade remain, the NV shall be based on the constructed value of the merchandise.'' INA contends that the Department has defined potential ''foreign like products'' in terms of bearing families. INA concludes that, where there are remaining HM sales in the same family, the Department should base NV on those sales rather than on CV.

INA notes that, in *AFBs VI*, the Department defended its methodology on the ground that it makes the ''foreign like product'' determination under the criteria of section 771(16) only once and that the result of the cost test is not a criterion in determining the foreign like product under section 771(16). INA contends that the Department's automatic reliance on CV when all identical matches are disregarded as below cost is inconsistent with its approach with regard to contemporaneity because the Department applies the contemporaneity rule as a criterion for comparability even though that rule is not included in the section 771(16) definition.

Torrington argues that the Department should follow its decision in *AFBs VI* and continue to resort to CV rather than HM family sales when all sales of identical bearings are disregarded pursuant to the cost test.

Department's Position: We disagree with INA. Section 771(16) of the Tariff Act directs us to select the foreign like product ''in the first'' of several categories: identical in physical characteristics, similar in physical characteristics and commercial value, or of the same general class or kind that can be reasonably compared. The Department interprets the reference in section 773(b)(1) of the Tariff Act that it base NV ''on the remaining sales of the foreign like product in the ordinary course of trade'' to mean the selected foreign like product, not a succession of foreign like products. Therefore, we have resorted directly to CV where we have disregarded all contemporaneous identical HM sales as below cost instead of determining whether contemporaneous sales of a less similar model would survive the cost test and remain available as comparators. We explained this practice in detail in *AFBs V* at 66490–91 and *AFBs VI* at 2111–2112.

We disagree with INA's suggestion that our practice of using CV when all identical matches are disregarded is inconsistent with our policy with regard to choosing contemporaneous matches. We conduct a search for sales of the best model for comparison within a contemporaneity window pursuant to section 773(a)(1)(A) of the statute, which directs that ''[t]he NV of the subject merchandise shall be the price described in subparagraph (B), *at a time reasonably corresponding to the time of the sale* used to determine the export price or constructed export price'' (emphasis added). We have a longstanding practice of considering sales within 90 days before and 60 days after the month of the U.S. sale to be acceptable as potential comparators (*see Certain Small Business Telephone Systems and Subassemblies Thereof from Korea: Final Results of Antidumping Administrative Review,* 57 FR 8300 (March 9, 1993); *Certain Circular Welded Carbon Steel Pipes and Tubes from Thailand: Final Results of Antidumping Administrative Review,* 61 FR 1332 (January 19, 1996); *AFBs III* at 39735). Thus, our determination of which merchandise will be considered the foreign like product is based on (1) the product categories set forth in 771(16) and (2) the ability to review contemporaneous sales as contemplated in 773(a)(1)(A).

5.B. Research and Development

Comment: Torrington notes that the SKF Group companies, *i.e.*, SKF France, SKF Germany, SKF Italy, and SKF Sweden, allocated the general research and development (R&D) expenses incurred by their European Research Center (ERC) based on proportionate share holdings in the facility. Torrington contends that, if the Department accepts this methodology, the Department must account for expenses attributable to the share holding in the ERC by the SKF Group's parent company, AB SKF.

Respondents argue that their allocation methodology is proper and consistent with determinations in prior segments of this proceeding. Regarding Torrington's allegation of under-reporting, respondents explain that their parent company holds shares in the ERC on behalf of SKF Sweden and that SKF Sweden has reported the general R&D expenses attributable to these shares.

Department's Position: We agree with respondents. In section A of SKF Sweden's questionnaire response, respondent identifies the shares to which Torrington refers as SKF Sweden's share in the ERC. SKF Sweden reported the R&D expenses attributable to these shares as part of its general and administrative expenses. Thus, based on record evidence we are satisfied that respondents allocated the ERC expenses properly. Accordingly, for the final results, we did not adjust the R&D expenses reported by these respondents.

5.C. Profit for Constructed Value

Comment 1: NSK, INA, FAG Germany, FAG Italy, SNR France, and Barden argue that the methodology the Department used in the calculation of CV profit is unlawful. According to respondents, section 773(e)(2) of the Tariff Act authorizes the Department to make this calculation using one of four methods, depending on the information on the record. Respondents contend that, while in the preliminary results the Department calculated a CV-profit ratio for each level of trade within each class or kind of product sold in the HM in the ordinary course of trade, this method is not authorized by section 773(e)(2)(A) of the Tariff Act. Citing to this provision, respondents claim that the profit calculation must be equivalent to the sum of profits ''in connection with the production and sale of a foreign like product.'' Respondents argue that ''foreign like product'' is a statutorily defined term of art equivalent to the first of three enumerated categories of merchandise as defined by section 771(16) of the Tariff Act and that these three categories are narrower than ''class or kind''.

FAG Germany, FAG Italy and SNR France disagree with the Department's assertion that the use of the phrase ''a foreign like product'' rather than ''the foreign like product'' allows it to aggregate total profits across each class or kind of merchandise and that the meaning of ''foreign like product'' remains the same in both cases, as defined in the statute regardless of the preceding article, citing the *Notice of Proposed Rulemaking,* 61 FR at 7335. Thus, respondents argue, although Congress knew the meaning of ''foreign like product,'' it adopted this term intentionally in place of ''class or kind.'' Respondents also contend that, in accordance with section 771(16) of the Tariff Act, the foreign like product must be produced in the same country by the same person, disallowing the

Department's method of including sales of merchandise they sold that other manufacturers produced. Respondents contend further that the SAA at 840 clears any ambiguity regarding the term ''foreign like product'' in section 773(e)(2)(A) of the Tariff Act by recommending the alternative methods of 773(e)(2)(B) in instances where 773(e)(2)(A) cannot be used either because there are no HM sales of the foreign like product or because all such sales are at below-cost prices.

Torrington counters that the Department need not change its policy with regard to the CV-profit calculation, claiming that ''foreign like product'' refers to the entire class of merchandise that meets the definitions of section 771(16) and not just the identical part number or family. It notes that such a similar reference is made to foreign like product with respect to statutory passages concerning the viability test at section 773(a)(1)(C). Torrington adds that the interpretation of ''foreign like product'' as a family would necessarily create a gap in the statutory scheme. As an example, petitioner describes a situation where, if family-specific profit could not be calculated, the use of profits on the ''same general category'' would never be considered because ''foreign like product'' is too narrow to constitute ''the same general category'' as directed in section 773(e)(2)(B) of the Tariff Act. Torrington continues by arguing that the use of the indefinite article ''a'' rather than the definite article ''the'' in section 773(e)(2)(A) of the Tariff Act is significant and is meant to refer to ''any'' foreign like product, as in more than one foreign like product. In addition, Torrington disagrees with respondents' argument that Congress replaced the term ''class or kind of merchandise'' deliberately in order to restrict the calculation of profit only to the foreign like product corresponding to a U.S. sale. Torrington contends that the removal of the term was simply to conform the terminology of the U.S. antidumping law to the international Antidumping Code. Finally, Torrington contends that the respondents' suggested methodology would resort to the application of alternative methodologies too soon in the hierarchy of preferable methods. Petitioner argues that section 773(e)(2)(B) of the Tariff Act outlines alternative profit methodologies for use only when the method described in section 773(e)(2)(A) of the Tariff Act cannot be used, as in instances where there are no HM sales of the foreign like product or all such sales are below cost.

Department's Position: We disagree with the respondents. As we stated in *AFBs VI*, respondents' definition of the term ''foreign like product'' is overly narrow with respect to its use in the CV-profit provisions. In applying the ''preferred'' method for calculating profit (as well as SG&A) under section 773(e)(2)(A) of the Tariff Act, the use of aggregate data that encompasses all foreign like products under consideration for NV results in a practical measure of profit that we can apply consistently in each case. By contrast, an interpretation of section 773(e)(2)(A) of the Tariff Act that would result in a method based on varied groupings of foreign like products, each defined by a minimum set of matching criteria shared with a particular model of the subject merchandise, would add an additional layer of complexity and uncertainty to antidumping proceedings without generating more accurate results. It would also make the statutorily preferred CV-profit methodology inapplicable to most cases involving CV. We discussed in the preamble to our final regulations that, although we recognize that there are other methods available for computing profit for CV under section 773(e)(2)(A) of the Tariff Act, we continue to believe that our method represents a reasonable interpretation of the statute. *See Final Rule*, 62 FR at 27359. We also note that this approach is consistent with our method of computing SG&A and profit under the pre-URAA version of the statute, and, despite the fact that the URAA revised certain aspects of the SG&A and profit calculations, we do not believe that Congress intended to change this particular aspect of our practice. Therefore, we have not changed our methodology for the final results. *See also Notice of Proposed Rulemaking*, 61 FR at 7335 (discussing the Department's practice for calculating profit (and SG&A) using aggregate figures).

Comment 2: FAG Italy, FAG Germany, SNR France, and Barden contend that the Department's CV-profit methodology of calculating profit on an aggregate basis for all foreign like products is most similar to the first alternative CV-profit methodology described in 773(e)(2)(B)(i) of the Tariff Act because it aggregates profits encompassing sales from multiple foreign like products. However, respondents contend, contrary to the Department's methodology, section 773(e)(2)(B)(i) does not limit the CV-profit calculation to sales in the ordinary course of trade. Citing the SAA at 841, respondents argue that the absence of any language in section 773(e)(2)(B)(i) of the Tariff Act referring to sales in the ordinary course of trade and the presence of this precise limitation in descriptions of the other profit methodologies necessitates the inclusion of sales outside the ordinary course of trade in methodologies using all sales of the same class or kind.

SKF argues that below-cost sales should be included in the calculation of CV profit when grouping products of the same general category (citing section 773(e)(2)(B)(i) of the Tariff Act). Because the Department has chosen to calculate profit on a class-or-kind basis rather than for each family (foreign like product), these respondents contend that the Department is without authority to exclude sales outside the ordinary course of trade such as below-cost sales.

SKF argues that, if the Department continues to exclude below-cost sales from the calculation of total profits for each class or kind of merchandise, it should include the COP for below-cost sales when calculating the profit ratio for each class or kind of merchandise. Before dividing total profits by the total COP of all sales producing those profits, respondents argue that the Department should add the COP for below-cost sales back into the total costs of production for each respective group of sales. Respondents argue that this would allow the Department to determine the profit rate per sale more accurately.

Torrington asserts that respondents' arguments with respect to the inclusion of below-cost sales in the calculation of CV profit under section 773(e)(2)(B) of the Tariff Act is inconsistent logically with their argument concerning section 773(e)(2)(A) of the Tariff Act. Torrington contends that under respondents' methodology, before calculating an overall aggregate profit under section 773(e)(2)(B) of the Tariff Act, the Department would first have to test all sales of identical and similar models to determine whether any sales were made in the ''ordinary course of trade.'' Torrington contends further that below-cost sales would first be excluded under section 773(e)(2)(A) before resorting to aggregate profit data under section 773(e)(2)(B).

Torrington argues that below-cost sales must be excluded for purposes of calculating CV profit and should not be included in the average-profit calculation as so-called zero-profit sales. Citing section 771(15) of the Tariff Act and the SAA, Torrington contends that inclusion of sales outside the ''ordinary course'' are not a proper basis for determining profit under section 773(e)(2)(A) of the Tariff Act. Torrington argues that the SAA also establishes that ''only'' ordinary-course-of-trade sales will be the basis for the profit calculation and, therefore, the

Department should not include the full costs of sales at a loss in the denominator of the profit-ratio calculation as this would make these part of the profit calculation.

Department's Position: We disagree with respondents that our CV-profit methodology is most similar to the first alternative CV-profit methodology described in 773(e)(2)(B)(i) of the Tariff Act based on our interpretation of ''foreign like product.'' We agree with Torrington that we should not include sales that failed the below-cost test in the calculation of profit for CV because these sales fall outside the ordinary course of trade. As we stated in the preliminary results, we have calculated CV profit using the profit methodology as stated in section 773(e)(2)(A) of the Tariff Act. This provision requires that we base profit on sales made in the ordinary course of trade which, in turn, do not include sales that we disregarded as a result of the below-cost test. See section 771(15) of the Tariff Act. Furthermore, we do not believe that we should retain the full costs of disregarded sales while setting those sales' profits to zero. The use of partial information from the sales would distort the profit rate for sales in the ordinary course of trade and frustrate the intent of the statute.

Comment 3: NSK and NSK/RHP argue that the Department erred when it calculated CV profit based upon the HM database. Respondents contend that the HM database consists of sample-week sales and is not representative of its HM profit experiences with respect to the class or kind of merchandise. NSK and NSK/RHP maintain that the SAA intended the Department to use Financial Statement profit when determining CV profit and that the Department must apply the preferred profit methodology at the model-specific or family-specific level or it must resort to one of the alternative profit methodologies.

Torrington rebuts that respondents offer no evidentiary or rational basis for concluding that the HM database is not representative of the profit experiences in the HM when sample week sales are reported.

Department's Position: We disagree with NSK and NSK/RHP. We rejected this argument in *AFBs VI*, stating that HM sales and cost data provided by respondents on a sampled basis does not render such data inappropriate for purposes of calculating CV profit. Pursuant to the statutory authority provided at section 777A of the Tariff Act, we routinely use data in our analysis that has been reported on a sampled basis. Thus, the statute does not explicitly provide for such an automatic elimination of these profit methodologies in such cases. *See* our response to Comment 1 of section 6.C of *AFBs VI*, 62 FR at 2112, for a more comprehensive discussion on this topic.

Comment 4: SNR France argues that the CV profit the Department calculated for CRBs is based on U.S. sales rather than on HM sales. Moreover, SNR France asserts that this calculation is unlawful because it is not based on the actual profit that SNR France earns on HM sales of the foreign like product made in the ordinary course of trade. Specifically, SNR France contends that the Department based its profit calculation on costs taken from SNR France's U.S. CV database which, SNR France argues, is a mere microcosm when compared to its total HM sales. SNR France suggests that the Department should instead calculate a profit ratio based on its financial statements.

Torrington points to the fact that the Department did not request COP data from SNR France for CRBs. Torrington states that, while SNR France suggests that financial-statement data would be a more appropriate proxy for the entire profit calculation, Torrington contends that SNR France failed to propose appropriate ratios based on the financial statements. Moreover, Torrington asserts that this data would necessarily include non-scope products.

Department's Position: We disagree with SNR-France. We must balance the need to calculate an accurate margin with the need to reduce the burden on respondents. Because we did not request complete COP data for SNR-France's sales of CRBs, we were unable to calculate CV profit under the ''preferred methodology'' of section 773(e)(2)(A). Instead, we calculated CV profit based on the following methodology.

We subtracted the home market COP from the home market sales value. Home market COP consists of three costs: COM, interest expenses, and G&A expenses. First, we aggregated the expenses reported in the CV dataset. Then, we calculated the ratio of variable COM to total COM based on data contained in the CV dataset. We applied this ratio to the variable COM reported in the home market sales dataset. Thus, we created a reasonable proxy for home market total COM. Likewise, we calculated a ratio of G&A and interest expenses to the total COM reported in the CV dataset. We multiplied each of these ratios by the home market total COM. Finally, we summed these amounts to arrive at total home market COP.

This methodology results in a reasonable estimation of COP, since the major element in COP, the variable COM, is an actual amount and the proxy is limited to fixed costs, G&A, and interest expenses. Thus, this is a reasonable methodology allowed under section 773(e)(2)(B)(iii).

We agree with Torrington that SNR-France's financial statements would contain data for non-scope merchandise. Thus, SNR's suggested methodology would be a proxy as well. The record does not support the conclusion that SNR-France's financial statements would form a more appropriate proxy nor has SNR-France established that the Department's current methodology is distortive. Therefore, we have not changed the methodology we used in our preliminary results.

Comment 5: NPBS contends that the Department calculated a level-of-trade-specific profit mistakenly for purposes of calculating CV. NPBS asserts that profit for CV should not be calculated by level of trade, particularly when there is no match between HM and U.S. levels of trade. NPBS argues further that calculating CV profit by level of trade is contrary to law. Citing section 733(e) of the Tariff Act, NPBS asserts that the statute says nothing about level of trade in describing how to calculate CV. NPBS also asserts that the SAA says nothing about calculating profit for CV on a level-of-trade basis. To the contrary, citing the SAA at 839–841, NPBS asserts that Congress intended the Department to calculate profit for CV on a company-wide basis. NPBS concludes that it would be bad policy to calculate CV profit by level of trade because it would make dumping calculations unpredictable.

Torrington requests that the Department reject NPBS's arguments. Torrington asserts that the lack of explicit instructions in the law does not prevent the Department from calculating profit for CV on a level-of-trade basis. In support of this argument, Torrington cites *Mobile Communications Corp. of America* v. *F.C.C.*, 77 F.3d 1399, 1404–05 (D.C. Cir. 1996). Torrington concludes that the methodology represents a reasonable interpretation of the statute's requirements.

Department's Position: We agree with petitioner. Profit for CV should be calculated on a level-of-trade basis because the level-of-trade-specific profit calculation recognizes that profit levels may differ depending on the level of trade. Thus, in the final results we calculated NPBS's profit for CV on a level-of-trade-specific basis for each class or kind of merchandise. *See* our response to Comment 1 of section 6.C of

AFBs VI, 62 FR 2081 at 2112, for more information on our methodology for the calculation of profit for CV.

5.D. Affiliated-Party Inputs.

Comment 1: NSK contends that the Department has no reasonable basis for requiring the submission of cost information on inputs from affiliated suppliers and should therefore accept the transfer prices of such products as NSK reported.

Torrington argues that the Department should reject NSK's argument for the reasons the Department set forth in detail in *AFBs VI.*

Department's Position: We disagree with NSK. NSK made an identical argument in the prior review with respect to this issue, which we rejected, and NSK offers no new arguments for altering our position. Pursuant to section 773(f)(2) of the Tariff Act, we generally use the transfer price of inputs purchased from an affiliated supplier in determining COP and CV, provided that the transaction occurred at an arm's-length price. In determining whether a transaction occurred at an arm's-length price, we generally compare the transfer price between the affiliated parties to the price of similar merchandise between two unaffiliated parties. If transactions of similar merchandise between two unaffiliated parties are not available, we may use the affiliated supplier's COP for that input as the information available as to what the amount would have been if the transaction had occurred between unaffiliated parties. In the case of a transaction between affiliated persons involving a major input, we use the highest of the transfer price between the affiliated parties, the market price between unaffiliated parties, and the affiliated supplier's cost of producing the major input. *See AFBs VI* at 2115. Therefore, we have not altered our methodology for these final results.

Comment 2: NSK argues that the Department should recognize the unique situation pertaining to a certain affiliated supplier of inputs and determine that purchases from this supplier were made at arm's-length prices.

Torrington argues that the situation pertaining to this supplier does not demonstrate that purchases from the supplier were necessarily made at arm's-length prices.

Department's Position: We disagree with NSK. NSK made an identical argument in the prior review with respect to an affiliated supplier, which we rejected, and offers no new arguments to convince us to alter our position. *See AFBs VI* at 2115. There is no evidence on the record that indicates that purchases from this supplier were necessarily made at arm's-length prices. Therefore, we have made no change in our treatment of this supplier for the final results.

Comment 3: NSK argues that the Department should not regard a certain type of input as a major input because this type of input does not meet the statutory definition of major inputs.

Torrington argues that NSK does not dispute that this type of input is an essential component of many types of bearings and that NSK's reported data demonstrates that this type of input can account for a significant percentage of the cost of manufacture.

Department's Position: We disagree with NSK. NSK made an identical argument in the prior review with respect to this type of input, which we rejected, and offers no new arguments for altering our position. *See AFBs VI* at 2116. Therefore, we have made no change in our treatment of this type of input for the final results.

Comment 4: Nachi contends that the Department should not reject its reported cost of affiliated-party inputs. Nachi asserts that the Department misunderstood its characterization of its methodology for reporting such costs and the underlying reasons for using this methodology. Nachi explains that its affiliated suppliers were small, captive producers that lacked the capability to provide product-specific cost information. Nachi contends that, if the affiliate is profitable during the POR, the transfer price must necessarily be above the affiliate's cost of producing the input. By contrast, if an affiliate had operated at a loss during the POR, Nachi asserts that it would have reported the COP for the input. Nachi notes that it reported the transfer price for purchases from all affiliates because all of its affiliates were profitable during the POR. Nachi also asserts that the Department accepted this methodology in every prior review in which Nachi participated.

Torrington argues that the overall profitability of an affiliated supplier is not determinative as to whether the transfer prices of particular inputs are above cost or reflect arm's-length prices. Torrington notes that Nachi did not provide prices of similar inputs it obtained from unaffiliated suppliers. Torrington further contends that the Department's preliminary determination to reject Nachi's reported cost of affiliated-party inputs is in accordance with the precedent the Department set in *AFBs VI* at 2115.

Department's Position: We disagree with Nachi. We require costs to be reported on a product-specific basis. Though Nachi's affiliated suppliers may have been captive to Nachi during the POR and though these suppliers may have all been profitable, the fact remains that some inputs may have been sold at transfer prices which were below the affiliate's cost of producing the input during the POR. Finally, we note that each review stands alone and the fact that we accepted Nachi's methodology in prior reviews is not determinative of which methodology we use in this review. Because Nachi did not report its data in such a way that we could determine whether all affiliated-party inputs were sold at a transfer price which was below the affiliate's cost of producing the input on a product-specific basis, for these final results we have used the facts available as described in our preliminary analysis memorandum for Nachi dated March 28, 1997.

Comment 5: Torrington contends that NMB/Pelmec reported COP and CV for all models using transfer prices for inputs purchased from affiliated parties. Torrington asserts that the transfer price of the input material did not exceed the COP of that material in all cases. Torrington argues that, in conformance with the policy the Department enunciated in *AFBs VI*, the Department should use the higher of the transfer price, cost, or market value for major inputs NMB/Pelmec obtained from its affiliated companies.

NMB/Pelmec rebuts that the Department is not strictly required to use COP in every instance, especially in the case where transfer price exceeds COP for the vast majority of inputs. Citing the preamble of *Antidumping Duties; Countervailing Duties Final Rule*, 62 FR 27296, 27362 (May 19, 1997), NMB/Pelmec contends that the Department has the discretion to use transfer prices after considering the specific facts of each case. NMB/Pelmec also notes that, in other comparable aspects of the antidumping margin calculation, such as the below-cost test for HM sales, the Department does not automatically exclude all below-cost prices as long as the vast majority are above cost.

Department's Position: We agree with Torrington that we should have used COP in cases where COP exceeded transfer price for the value of affiliated-party major inputs for NMB/Pelmec. We have made this change for the final results. *See* our response to comment 1 of section 6.D of *AFBs VI* at 2115 for a comprehensive discussion of our practice with regard to affiliated-party inputs.

Comment 6: Torrington argues that NTN Japan purchased components from an affiliated supplier at prices below the cost of producing such items. Torrington states that it based its examination on a submission made by NTN Japan's affiliated party for the record of these reviews. Torrington argues that the Department should restate NTN Japan's reported COP to reflect arm's-length values for those models in which NTN Japan purchased components from this affiliated party. Torrington also maintains that the Department should request all necessary information from NTN Japan to restate such values or apply facts available if NTN Japan is unable to provide such information.

NTN Japan argues that, while it received a public version of the argument regarding transfer prices from NTN Japan's affiliated supplier, it did not receive the full argument because Torrington had deleted the proprietary information. NTN Japan objects to its denial of access through its counsel to this information and notes that NTN Japan's affiliated party permitted such access to the original submission from which Torrington conducted its analysis.

Department Position: We agree with Torrington in part. After re-examining the record, we determine that NTN Japan's costs should be restated because the transfer prices from some affiliated parties were below the affiliate's COP. However, since it is unclear from the record for which models NTN Japan uses the purchased components, we are unable to restate NTN's costs on a model-specific basis. Therefore, we are applying facts available to NTN Japan's costs. Because of the proprietary nature of the information we are using, we cannot discuss the facts available we are applying in this public notice. *See* NTN Japan's final results analysis memorandum dated September 22, 1997 for a complete discussion of the facts available we are using to restate NTN Japan's costs. Finally, while we note NTN Japan's objection to being denied access to the proprietary version of Torrington's arguments, we could not redress the situation due to the circumstances surrounding the treatment of proprietary information in this case. For a complete discussion of these circumstances, see Memorandum from Greg Thompson to the File dated September 22, 1997.

5.E Abnormally High Profits

Comment 1: Torrington argues that no respondent has shown adequately that profits it earned on certain sales were aberrational or abnormal or otherwise should be disregarded for purposes of calculating CV profit. Torrington notes that the statute does not address abnormal profits but provides that sales which are outside the ordinary course of trade should be excluded from the calculation of NV and likewise the calculation of CV profit. Torrington states that, once the Department has excluded sales outside the ordinary course of trade from the calculation of NV, the Department has already ensured that it will use no sales with abnormally high profits in its CV-profit calculation. Torrington therefore concludes that it is illogical for the Department to re-examine the remaining sales for abnormally high profits before calculating a CV-profit rate.

Similarly, Torrington contends that, if a respondent fails to submit adequate information to establish that particular sales were outside the ordinary course of trade, the Department need not re-examine the same sales to determine whether some sales involved abnormally high profits. Torrington concludes that, because it is rational to maximize profits, evidence that maximum profits were extracted on some subset of total sales is not alone sufficient to indicate that profits were abnormal and that there is no profit margin that is abnormally high simply by reference to the costs or prices in the abstract.

Citing section 773(a)(1)(B) of the Tariff Act, INA, NSK, NSK/RHP, NTN, and SKF argue that the Department, in determining NV, must disregard sales which have ''abnormally high'' profits outside the ordinary course of trade. NTN, NSK, and NSK/RHP claim that the Department's new regulations at 351.102(b) and the SAA at 164 give the Department clear instruction to exclude sales made with abnormally high profits and sales made at aberrational prices as outside the ordinary course of trade. INA and NTN argue that sales with abnormally high profits are a category of transactions whose inclusion in the profit calculations would result in unrepresentative price comparisons and distortive results, citing the SAA and *IPSCO* v. *United States*, 714 F. Supp. 1211, 1217 (1989). INA, NTN, and SKF assert that Torrington is incorrect in arguing that, once the Department has eliminated some sales which are outside the ordinary course of trade, it does not need to reexamine the remaining sales to determine if they may have abnormally high profits and are therefore also outside the ordinary course of trade. Rather, respondents contend, the presence of abnormally high profits supports the conclusion that such sales are outside the ordinary course of trade and, therefore, must be excluded from the calculation of NV. NSK and NSK/RHP assert that the benchmark for concluding that sales are outside the ordinary course of trade due to the presence of abnormally high profits is not abnormally high profits *per se* but rather an analysis of the characteristics of the transaction in the context of the specific market.

FAG responds that abnormal profit ratios and inflated CVs resulted from the Department's unlawful calculation of CV profit on a class-or-kind basis rather than on a foreign-like-product basis (discussed at Comment 1 of section 5.C. (Profit for CV), above). Therefore, FAG argues, the Department has calculated abnormally high profit rates unlawfully beyond a reasonable degree of normality. FAG maintains that the URAA requires the Department to first calculate profit earned in connection with the production and sale of a foreign like product, citing section 773(e)(2)(A) of the Tariff Act. FAG argues that, despite the Department's purported use of this ''foreign like product'' methodology, the Department actually determines profit by reference to total revenue and total cost of all class-or-kind sales which pass the cost test. FAG argues that, because the Department determined profit rates on a class-or-kind basis according to section 773(e)(2)(B)(i), it should not exclude from the calculation of profit those sales made below cost while including sales with abnormally high profits. By eliminating sales in this manner, FAG contends, the Department has created profit rates which do not reflect ordinary experience. FAG argues that determination of profit rates on a category of sales more general than the foreign like product requires inclusion of all sales regardless of whether they were made in the ordinary course of trade. FAG requests that the Department recalculate profit rates based on all sales of the product group without regard to whether those sales were made in the ordinary course of trade.

Department's Position: We agree with Torrington that no respondent has adequately shown that profits earned were aberrational or abnormal or otherwise outside the ordinary course of trade. As in past reviews, the fact that a respondent identifies sales as having abnormally high profits does not necessarily render such sales outside the ordinary course of trade. Profits are not automatically abnormally high and such sales are not automatically outside the ordinary course of trade for purposes of computing CV profit simply because certain HM sales had profits higher than those of other sales. In *Large*

Newspaper Printing Presses and Components Thereof, Whether Assembled or Unassembled, From Germany (61 FR 38166, July 23, 1996), we stated that, in order to determine that profits are abnormally high, there must be certain unique or unusual characteristics related to the sales in question. Verification of the designation of certain sales as having abnormally high profits merely proves that the respondent identified sales as having abnormally high profits in its own records. This evidence does not indicate that such sales were made outside the ordinary course of trade for purposes of calculating NV in these reviews. Accordingly, we excluded no HM sales from the CV-profit calculation on the basis of finding abnormally high profits.

We disagree with FAG's contention that abnormal profit ratios and inflated CVs resulted from our unlawful calculation of CV profit on a class-or-kind basis rather than on a foreign-like-product basis. See our position with respect to ''Profit for Constructed Value'' above. With respect to FAG's argument that we should not have eliminated sales below cost from our analysis while including those sales it believes to have been made with abnormally high profits, we note that we have followed the requirements set forth in section 773(e)(2)(A) of the Tariff Act. By calculating the profit earned in connection with the sale of the foreign like product, we have examined HM sales properly to determine if they were made within the ordinary course of trade. Upon examining these sales, we have eliminated from our consideration all below-cost sales disregarded under section 773(b) of the Act, as these fall outside the ordinary course of trade. As stated above, respondents have not provided adequate evidence to support the conclusion that any sales which resulted in abnormally high profits were outside the ordinary course of trade. No unique or unusual characteristics related to these sales were demonstrated by any respondent. For these reasons, we have not excluded HM sales on the basis of abnormally high profits. Once we have eliminated sales outside the ordinary course of trade from the HM database, our profit methodology reflects the profit experience fully of the companies for those sales made within the ordinary course of trade and is, therefore, reasonable.

Comment 2: INA claims that there was one specific sale in the HM in the INA–FRG HM sales list that by any measure was made at an aberrational price with an abnormally high profit. INA argues that this is a sufficient basis for concluding that the sale was outside the ordinary course of trade and should be excluded from the Department's final margin calculations. INA cites section 773(a)(1)(B) of the Tariff Act, believing that it provides examples of this type of transaction that may be considered to be outside the ordinary course of trade. INA also points to *Large Newspaper Printing Presses and Components Thereof, Whether Assembled or Unassembled, From Germany* (61 FR 38166, July 23, 1996), where the Department rejected arguments that sales with abnormally high profit margins should be excluded from NV, saying that ''numerical profit amounts'' alone were not enough to show that the profits were abnormally high and that ''there must be certain unique or unusual characteristics related to the sales in question'' (at 38178). However, INA asserts that that case should not be read to exclude the possibility that in a particular case ''numerical profit amounts'' alone would be sufficient, since the SAA at 164 specifically identifies abnormally high profit, without more, as a circumstance which would qualify as making a sale outside the ordinary course of trade. In sum, INA asserts that the use of this sale in the calculation of NV would result in irrational and unrepresentative results which is what the ''ordinary course of trade'' requirement of the statute is intended to prevent. Accordingly, INA contends, the Department should exclude the transaction from its final calculations.

In rebuttal, Torrington argues that the Department should not exclude any HM sales allegedly made at aberrational prices or with abnormal profits. Torrington also refers back to its argument that no respondent has shown adequately that profits each earned on certain sales were ''aberrational'' or ''abnormal'' or otherwise should be disregarded for purposes of calculating CV-profit rates for these reviews.

Department's Position: We disagree with INA. The presence of profits higher than those of numerous other sales does not necessarily place the sale outside the ordinary course of trade for purposes of computing CV profit. In order to determine that a sale is outside the ordinary course of trade due to abnormally high profits, there must be certain unique and unusual characteristics related to the sale in question. However, the respondents have provided no information other than the numerical profit amounts to support their contention that certain HM sales had abnormally high profits. Accordingly, we have not excluded INA's specific sale from the CV-profit calculation.

5.F. Credit and Inventory Costs

Comment 1:

NSK and NSK-RHP claim that the Department made a clerical error in its calculation of imputed credit and inventory carrying costs for CV. Respondents contend that this clerical error understates imputed credit and inventory carrying costs since the ratios the Department used to calculate these adjustments are based on a price denominator that includes movement charges while the values to which the Department applied the ratios are net of movement charges. They request that the Department correct this error by either removing movement charges from the price denominator used in the ratio calculation or adding movement charges to the values to which the Department applies these ratios.

SKF France, SKF Germany, SKF Italy, SKF Sweden, and Torrington agree that the Department committed a clerical error in its calculation of imputed credit and inventory carrying costs for CV. These parties also agree with NSK's and NSK-RHP's suggested methodology for correcting the error.

Department's Position: We disagree with the interested parties' assertion that the methodology we applied for the preliminary results was a clerical error since it was intentional. However, upon considering all comments on our methodology, we have decided to make a change to our methodology since it understates the imputed credit and inventory carrying costs we calculated for CV. To correct the problem, we deducted movement charges from the denominator of the ratio calculations we used to derive imputed credit and inventory carrying costs for CV. This ensures that the ratios, and values to which we apply them, are comparable.

Comment 2: SNR France asserts that the Department used a price-based denominator, *i.e.*, total HM price, erroneously in the calculation of ratios used to derive imputed credit and inventory carrying costs for CV. SNR France contends that since the Department applies these ratios on a cost basis it must also calculate the ratios on a cost basis by using HM total COP in the denominator. SNR France notes that the Department made this change for the *Amended Final Results of Antidumping Duty Administrative Reviews,* 62 FR 34201 (June 25, 1997) in *AFBs VI.*

Department's Position: As we explained in response to Comment 1 of this section, a change in the denominator of the ratio calculation is necessary for the sake of comparability. However, we do not agree with the

change SNR France requested. To derive imputed credit and inventory carrying costs for CV, which is a surrogate for HM price, we apply the ratios to a CV that includes the COP, direct selling expenses, indirect selling expenses, commissions, profit, and packing. Thus, the CV we use is essentially on the same basis as the price in the denominator of the ratio calculation because both include and exclude the same expenses (except movement expenses, an error we corrected for these final results pursuant to Comment 1 of this section). Furthermore, we believe that an allocation based on price is more appropriate than one based on cost because we calculate imputed expenses by applying an expense factor to the price, not the cost, of transactions.

5.G. Other Issues

Comment 1: Torrington argues that, in the instant review, NTN allocated its reported COP and CV selling expenses on the basis of levels of trade. Torrington contends that, in the 1994/95 review, with respect to U.S. indirect selling expenses, the Department did not accept this allocation method because NTN could not demonstrate how these expenses were attributable to different levels of trade. Torrington asserts that, for these final results, the Department should reach the same conclusion as it did in the *AFBs VI* review and recalculate NTN's COP and CV selling expenses.

NTN argues that, although the Department did not accept NTN's selling expenses based on level of trade in *AFBs VI*, the Department did permit such level-of-trade-based selling expenses in previous reviews. NTN also argues that, in the most recently completed TRB review in which it was involved, the Department accepted its level-of-trade-based selling expenses and even stated that they ''prevent distortion'' (*citing Tapered Roller Bearings, Finished and Unfinished from Japan; Final Results of Administrative Review*, 61 FR 57629, 57636 (November 7, 1996)). NTN points out that the Department did not make any changes in the preliminary results of review to NTN's reported level-of-trade-based HM selling expenses and states that the Department normally uses such selling expenses in its CV calculations. Further, NTN argues that, absent Torrington raising the argument that NTN's HM selling expenses be denied, the Department should accept NTN's reported level-of-trade-based selling expenses.

Department Position: We agree with Torrington that these expenses should not be allocated based on level of trade. The CIT remanded this issue to the Department in *The Timken Company* v. *United States* on May 31, 1996 (*see* Slip Op. 96–86 for the 1990/92 reviews of the order on TRBs over four inches from Japan). The remand directed us to recalculate NTN's indirect selling expenses without regard to level of trade or explain our reasons why we thought the expenses were allocated correctly. In our remand, we explained that, because we could not determine on the basis of the information provided by NTN whether expenses varied according to level of trade, we recalculated the expense information without regard to level of trade. On July 3, 1997, the CIT affirmed our remand (*see* Slip Op. 97–87). Consistent with our remand determination in the TRB case, because NTN has not provided us with the necessary information for this review period to determine whether the expenses varied according to level of trade, we have recalculated its expenses so that they do not reflect levels of trade (*see* Analysis Memo dated September 22, 1997).

6. Further Manufacturing

Comment: Although SKF does not challenge the Department's methodology in applying the special rule of section 772(e) in these reviews, it suggests that the methodology for determining whether there are sufficient quantities of sales of non-further-processed subject merchandise for calculating a margin may not be an appropriate test under all circumstances.

Torrington rebuts that, since SKF does not contest the Department's preliminary results and SKF's comment is not based on the current record, the Department need not address the issue.

Department's Position: Since there is no information or argument on the record demonstrating that our methodology in this case is unreasonable, we have not changed our methodology for these final results. However, as a general matter, we note that the statute has left to our discretion how to determine whether a sufficient quantity of sales exists. We intend to develop our practice in this area on a case-by-case basis.

7. Packing and Movement Expenses

Comment 1: NSK argues that expenses associated with repacking in the United States are not selling expenses and thus should not be included in the selling expenses the Department uses to calculate CEP profit. Citing the statute at sections 772(c) and (d), NSK contends that repacking expenses are deducted pursuant to section 772(c)(2)(A) of the statute and thus should not be included in the CEP-profit calculation. In addition, NSK alleges that the Department has stated this implicitly by asking for packing and repacking expenses in a part of its questionnaire which is separate from selling expense.

Torrington argues that the Department treated repacking expenses as selling expenses correctly for the purposes of calculating CEP profit. Torrington notes that NSK reported that it normally does not perform repacking for U.S. sales but that it does some repacking to accommodate orders for smaller distributors. Torrington contends that this characterization is consistent with the Department's treatment of repacking as a selling expense.

Department's Position: We disagree with NSK. As NSK notes, section 772(c)(2)(A) of the Tariff Act covers ''transportation and other expenses, including warehousing expenses, incurred in bringing the subject merchandise from the original place of shipment in the exporting country to the place of delivery in the United States.'' *See* SAA at 153. We do not view repacking expenses as movement expenses. The repacking of subject merchandise in the United States bears no relationship to moving the merchandise from one point to another. The fact that repacking is not necessary to move merchandise is borne out by the fact that the merchandise was moved from the exporting country to the United States prior to repacking. Rather, we view repacking expenses as direct selling expenses respondents incur on behalf of certain sales which we deduct pursuant to section 772(d)(1)(B) of the statute. Section 772(d)(1)(B) of the statute directs that CEP shall be reduced by ''expenses that result from, and bear a direct relationship to, the sale, such as credit expenses, guarantees, and warranties.'' We regard repacking expense as a direct selling expense because it was performed on individual products in order to sell the merchandise to the unaffiliated customer in the United States. Presumably, if a respondent could have sold the merchandise without repacking it, the respondent would have done so. Thus, it is an expense associated with selling the merchandise.

Section 772(d)(1)(B) of the Tariff Act does not limit direct selling expenses deducted from CEP to credit expenses, guarantees or warranties. Furthermore, as noted in the SAA, under section 772(d), CEP will be calculated by reducing the price of the first sale to an unaffiliated customer in the United States by the amount of any selling expenses which result from, and bear a

direct relationship to, selling activities in the United States. Finally, the format of our questionnaire is not germane to our analysis in determining how we treat reported expenses. Accordingly, we have continued to include repacking in the pool of selling expenses we use to calculate CEP profit.

Comment 2: Torrington asserts that NTN's reported HM packing expense is overstated based on a comparison it made between the information NTN and several other Japanese respondents provided. Torrington determined these rates by dividing the reported packing expenses by the reported gross unit prices. Torrington also asserts that NTN included expenses other than packing in its reported packing expense. In addition, Torrington alleges that NTN did not provide all of the worksheets necessary to support the manner in which NTN calculates its reported packing expense and states that, given this information, it cannot determine whether exports were included in the reported expense. Torrington maintains that, if exports were included in the calculation of NTN's packing expense, this expense may be based, in part, on transfer prices which could yield distortive figures. Further, Torrington asserts that NTN did not allocate its packing expense accurately. Torrington maintains that NTN did not adhere to the Department's requirement, as specified in its questionnaire, to report the expense based on identifiable costs. Torrington suggests that, for the above-mentioned reasons, the Department should either recalculate this expense or use the lowest packing rate from any other Japanese respondent.

NTN contends that it reported its HM packing expense accurately. NTN states that the experience of other Japanese companies has no bearing on the actual packing expense NTN incurred. NTN also states that, even if expenses other than packing were included in its reported packing expense, such expenses are negligible and, therefore, would have little impact on the reported packing expense. In addition, NTN argues that Torrington's allegation that NTN's packing expense includes export sales is incorrect. NTN maintains that the Department verified this expense and found no discrepancies with regard to this expense. NTN argues that it allocated its packing expense correctly and states that Torrington's suggestion that the Department recalculate this expense is baseless.

Department Position: Other respondents' packing costs are irrelevant to determining the accuracy of NTN's claimed amounts. We verified the calculation and allocation of NTN's packing expenses and found them to be reasonably undistortive (*see* verification report dated May 8, 1997, at 6). Therefore, we have accepted NTN's packing expenses as they were submitted.

8. Affiliated Parties

Comment 1: NPBS states that the Department should not treat a certain customer as affiliated. NPBS explains that the apparent basis for such treatment is that the customer's stockholding in NPBS barely meets the 5-percent threshold in 771(33)(E) of the statute when only the stock outstanding as of the time of the review is taken into account. NPBS claims that, in fact, the shares were previously held by employees of the NPBS company in question that would have taken the customer's shareholding below the 5-percent threshold. NPBS argues that, when some employees retire, their shares temporarily are converted into treasury stock but are then re-issued. NPBS claims that the Department should have included these shares in the denominator for the 5-percent test and, therefore, the Department would not have found the customer to be affiliated. NPBS contends that the customer's minimal shareholding does not place it in a position to satisfy the ''control'' criterion of 771(33)(G) of the Tariff Act and, accordingly, the Department should not treat the customer as affiliated.

Torrington responds that NPBS's argument should be rejected. Torrington explains that the Department applied its test correctly on the basis of facts observable and verifiable, rather than on speculation that the company expects to reissue certain stock, effectively reducing the percentage share of the customer.

Department's Position: We agree with petitioner. For these final results, we have continued to treat NPBS and the customer in question as affiliated. In accordance with section 771(33)(E) of the Tariff Act, the Department employs a 5-percent stock-ownership rule to determine whether two parties are affiliated. The party in question stated, and we verified, that during the POR it held 5 percent of the outstanding stock of NPBS. Once a party attains 5-percent ownership, for whatever reason, the Department determines that the parties are affiliated. Therefore, we have continued to treat the two companies as affiliated.

Comment 2: Torrington contends that the Department should not excuse NTN from obtaining sales information from its affiliated resellers in the HM. Torrington argues that NTN's excuses regarding the size of its resellers, its legal inability to obtain proprietary information from companies in which it holds a minority interest, the time involved to obtain such information, and the insignificant impact this information would have on the calculated margin are insufficient. Torrington also dismisses NTN's argument that the Department permitted NTN's reporting of sales to resellers in prior reviews because, Torrington states, each review is a separate proceeding. Torrington maintains that NTN has failed to demonstrate the arm's-length nature of such sales. Torrington argues further that, rather than disregard such sales when they fail the arm's length test, the Department should apply facts available to NTN's sales to affiliated resellers. Torrington also argues that, if the Department does not apply facts available to such sales, it should exclude such sales from the final margin calculations.

NTN contends that the application of facts available is not warranted because it provided responses to the Department's questionnaires and, as per the questionnaire, notified the Department of the difficulty involved in obtaining sales information from its affiliated resellers. NTN also argues that the Department did not request that NTN provide the sales information but, rather, requested an explanation concerning NTN's inability to obtain this information which it provided subsequently.

Department's Position: We disagree with the petitioner. NTN notified us of the sales to affiliated customers in the HM prior to answering our questionnaire. Given that these sales constituted a small percentage of NTN's HM sales and that collecting the data was not possible, we determined that NTN should report the sales to its affiliates. In the preliminary results, we conducted an arm's-length test and, in accordance with section 773(f)(2), we disregarded those sales which were not made at arm's-length prices. Based upon these facts and our determination not to request data concerning sales to unaffiliated customers, we have determined that the application of facts available is not warranted in this case.

9. Sample Sales and Prototypes/Zero Price Transactions

On June 10, 1997, the Court of Appeals for the Federal Circuit (CAFC) held that the term ''sold'' requires both a transfer of ownership to an unrelated party and consideration. *NSK Ltd.* v. *United States*, 115 F.3d 965, 975 (CAFC 1997) (*NSK*). The CAFC determined that samples which NSK had given to

potential customers at no charge and with no other obligation lacked consideration. *Id.* Moreover, the CAFC found that, since free samples did not constitute ''sales,'' they should not have been included in calculating U.S. price.

In light of the CAFC's opinion, we have reevaluated and revised our policy with respect to sales of samples. Therefore, pursuant to the CAFC's opinion, the Department will now exclude sample transactions, transactions for which a respondent has established that there is either no transfer of ownership or no consideration, from the dumping calculations.

This new policy does not mean that the Department automatically excludes from analysis any transaction to which a respondent applies the label ''sample.'' In fact, for these reviews, we determined that there were instances where it is appropriate not to exclude such alleged samples from our dumping analysis. It is well-established that the burden of producing support rests with the party in possession of the needed information. *See, e.g., NTN Bearing Corporation of America* v. *United States,* 997 F.2d 1453, 1458–59 (CAFC 1993), (citing *Zenith Elecs. Corp.* v. *United States,* 988 F.2d 1573, 1583 (CAFC 1993), and *Tianjin Mach. Import & Export Corp.* v. *United States,* 806 F. Supp. 1008, 1015 (CIT 1992)). In several cases, as discussed below, respondents failed to demonstrate or to submit documentation to show that their claimed sample sales lacked consideration. When respondents failed to support their sample claim, we did not exclude the alleged samples from our margin analysis.

With respect to HM sales, in addition to excluding sample transactions which do not meet the definition of ''sales,'' we may exclude sales designated as samples or prototypes from our analysis, pursuant to section 773(a)(1) of the Tariff Act, when a respondent has provided evidence demonstrating that the sales were not made in the ordinary course of trade as defined in section 771(15). We have addressed comments regarding ordinary course of trade separately in the section titled ''Ordinary Course of Trade.''

With regard to assessment rates, in order to ensure that we collect duties only on sales of subject merchandise, we included the entered values and quantities of the sample transactions in our calculation of the assessment rates and set the dumping duties due for such transactions to zero. We have done this because U.S. Customs will collect the *ad valorem* (or per-unit, where applicable) duty-assessment rate on all entries of subject merchandise regardless of whether the merchandise was a sample transaction. However, to ensure that sample transactions do not dilute the cash deposit margin, we excluded both the calculated U.S. prices and quantities for sample transactions from our calculation of the cash deposit rates.

Comment 1: Torrington argues that the CAFC's recent determination in *NSK* does not require a modification of the preliminary results and that the Department should continue to include in the U.S. database free samples which respondents gave to parties in the United States. Torrington argues further that the Department rejected respondents' claims properly that certain sales should be excluded based upon the information contained in respondents' questionnaire responses. Torrington maintains that negative inferences could be made in respondents' questionnaire responses where respondents did not supply the requested information. Torrington maintains further that the Department should determine whether to exclude free samples from the sales database by distinguishing between situations where sample recipients undertake actual obligations or engage in parallel transactions and where the recipients remain free to purchase a product of their own accord.

NSK, NSK/RHP, SKF, FAG, and NTN respond that the *NSK* decision requires the Department to re-evaluate U.S. samples and exclude all sample sales from the U.S. database. Respondents argue that the *NSK* decision held that a transfer of a zero-priced sample lacks consideration and does not constitute a sale; therefore, they argue, the Department cannot use such transfers in the dumping analysis. NSK and NSK/RHP contend further that the Department must apply the ordinary meaning of ''sale'' to the antidumping law, which involves not only the transfer of ownership but also the payment, or promise, of consideration.

NSK, NSK/RHP, SKF, FAG, and INA argue that the Department's requirement that respondents report free samples is not based on the information presented in their questionnaire responses. Respondents maintain that the Department's position regarding samples sales is based on the assertion that giving away a sample constitutes a sale for purposes of the antidumping duty statute unless proven otherwise. Respondents argue that, since the *NSK* decision overturned the Department's past practice, the Department should now exclude free samples from the U.S. database.

Department's Position: We agree with both parties in part. We agree with respondents that the *NSK* decision requires us to examine, in our determination of whether samples offered to customers at no charge constitute sales, whether the transactions involved both a transfer of ownership and consideration.

We also agree with Torrington that, in our determination of whether to exclude transactions identified as samples from the sales database, we should examine the information on the record to determine whether the recipients of the samples have undertaken actual obligations to purchase AFBs from the provider of the free bearings or whether the recipients remained free to purchase bearings of their own accord. This approach is consistent with the CAFC's decision which, in finding that NSK's samples given to potential customers at no charge lacked consideration, noted ''[t]hese customers were free to transact with NSK based solely on their whim.'' *See NSK,* at 975. As the CAFC noted, ''[c]onsideration generally requires a bargained for exchange'' (*Id.*) and we did not limit our review of consideration to the payment of a monetary price for the sample products.

With regard to NSK's reported U.S. sample and prototype transactions, it appears from the record that NSK did not receive consideration for sample transactions, but that NSK did receive consideration for its reported prototype transactions. *See* Proprietary Exhibit C–24 of NSK's September 9, 1996 response. Therefore, in accordance with the CAFC's decision in *NSK,* we have excluded NSK's reported sample transactions but not its claimed prototype transactions from its U.S. sales database. We note that we had removed NSK's reported HM sample transactions from its HM sales database for the preliminary results because NSK demonstrated that such transactions were outside the ordinary course of trade. We have not altered this treatment for the final results.

With regard to NSK/RHP's and Nachi's reported sample transactions, we examined the record and found no evidence that NSK/RHP and Nachi received consideration for such transactions. Therefore, we have excluded NSK/RHP's and Nachi's reported sample sales from their U.S. sales databases. NSK/RHP and Nachi did not report sample sales in the HM. With respect to FAG, INA, NTN, and SKF, we have addressed each company's specific arguments below.

Comment 2: Torrington contends that, if the Department determines, based upon the *NSK* decision, to exclude

certain sales claimed to be samples from the U.S. database, then the Department should require that the expenses incurred in connection with providing the free samples be accounted for as a direct selling expense to be attributed to the first sales transaction following the sample transaction. Torrington contends that, where this approach is not appropriate, the Department should attribute the expense (based on the COP of the sample) to all sales to the customer who received the sample and should cover the full COP of the sample.

NSK, NSK/RHP, SKF, INA, and FAG contest Torrington's proposal to treat the cost of samples as a direct selling expense. NSK and NSK/RHP respond that the Department should treat the cost of samples as an indirect advertising expense incurred in the general promotion of sales. They argue that the cost of a sample bearing is not properly charged to the recipient and that Torrington's approach is commercially unrealistic as it places more weight on the sample than it can reasonably bear. NSK, NSK/RHP, and SKF argue that the provision of free samples is not linked to specific sales; many factors drive the decision to purchase bearings. NSK and NSK/RHP contend further that, under Torrington's approach, if samples are provided and no sales occur, the expense would not be allocated to any U.S. sales.

SKF argues that, given the *NSK* decision, the Department need not inquire whether expenses associated with free samples were reported as indirect selling expenses. SKF maintains that, because the CAFC's holding in *NSK* did not rest upon the reporting of expenses, the Department should not base its decision to exclude sample sales upon whether the respondents had accounted for the related expenses. SKF contends that, if the Department disagrees with its argument, the Department should inquire about expense information only in future reviews. Finally, SKF argues that it reported its expenses related to sample sales as indirect selling expenses.

NTN argues that sample-related expenses cannot, as Torrington suggests, be attributed to the first sale following the sample transaction because there can be no selling expenses associated with the transaction since there has been no sale.

FAG and INA respond that Torrington failed to explain why the cost of samples should be treated as a direct selling expense. FAG argues further that there is no need to report the cost of manufacturing the samples since the samples were not sold. In addition, FAG maintains that respondents have accounted for all U.S. and HM selling expenses, as required by the questionnaire.

Department's Position: We have determined that we should treat the cost of zero-priced samples as an indirect selling expense respondents incurred in the general promotion of sales. However, we examined the record for these reviews and compared the total entered value of sample transactions with the total pool of expenses respondents used to calculate indirect selling expenses and found the total entered value of the sample transactions for all respondents for which we eliminated zero-price samples for these final results to be *de minimis.* Due to the burden of factoring these *de minimis* amounts into respondents' complex calculations of their indirect selling expenses, we did not recalculate indirect selling expenses to reflect the cost of zero-priced samples. Although we did not make this adjustment for these final results, in future reviews we will require respondents to include the costs associated with free samples as an indirect selling expense.

Comment 3: FAG Germany and FAG Italy request that the Department exclude all zero-priced U.S. sample transactions from the dumping margin calculation. Citing *NSK,* FAG Germany and FAG Italy contend that the sample transactions in their U.S. sales databases do not constitute ''sales'' since they provided them to potential customers at no charge.

Torrington contends that, since respondents repeatedly refer to zero-priced U.S. sample transactions as ''sales'' in their responses, the Department should draw an adverse inference and not exclude them from the margin calculation. Torrington also claims that respondents did not provide sufficient data regarding the individual sales they claimed for exclusion. Regarding FAG Italy, Torrington also contends that the Department should not exclude transactions from the margin calculation since the record is contradictory about whether this company had any such sample transactions. In support of this argument, Torrington cites to a statement in FAG Italy's supplemental questionnaire response that suggests that there are no samples in the U.S. sales database.

Department's Position: We have examined the record with regard to FAG Germany's reported sample transactions and found no evidence that FAG Germany received consideration for reported U.S. sample transactions. We did find evidence that indicated that FAG Germany received consideration for claimed HM sample transactions. Furthermore, FAG Germany did not demonstrate or submit documentation to show that its claimed HM sample sales were outside the ordinary course of trade. Therefore, in accordance with the CAFC's decision in *NSK,* we have excluded FAG Germany's reported sample sales from its U.S. sales database; however, we did not exclude FAG Germany's claimed HM ''samples'' from the calculation of NV.

With regard to FAG Italy, we have examined its HM and U.S. sales databases and found that FAG Italy did not identify any transactions as samples. Moreover, we also looked for zero-priced sales and found that FAG Italy did not report any zero-priced sales in either database. Therefore, we determined that FAG Italy's argument regarding sample sales is irrelevant with respect to these reviews.

Comment 4: The NTN companies (NTN Japan and NTN Germany) request that the Department exclude their sample sales from their U.S. sales databases in accordance with the CAFC's ruling in *NSK.*

Torrington argues that the Department must first determine whether a respondent has answered the Department's questions adequately regarding sample sales before making any exclusions. When all the information is not presented, Torrington asserts that the Department should assume that withheld information would have established that consideration (to which the court referred in *NSK*) was provided. Torrington maintains that such a fact pattern exists for the NTN companies and the Department should make adverse inferences. Torrington points to the NTN companies' questionnaire responses wherein they declined to answer questions regarding sample sales.

Department's Position: We agree with Torrington. As we noted in the introduction to this issue, the party in possession of the information has the burden of producing that information, particularly when seeking a favorable adjustment or exclusion. The NTN companies did not answer our questions regarding the purchase history of parties receiving samples. The NTN companies also did not answer our questions regarding the prices and quantities involved in sample sales. Rather, the NTN companies stated that the information is irrelevant. The answers to these questions would have aided us in determining whether the NTN companies received a bargained-for exchange from their U.S. customers.

Lacking knowledge of the details of these transactions, we cannot conclude that the NTN companies received no consideration for these alleged samples. In other words, because the NTN companies impeded our investigation of these transactions, we determined that an adverse inference is appropriate. Therefore, for these final results, we have included the NTN companies' sample sales in their respective U.S. sales database.

Comment 5: SNR France requests that the Department exclude its sample sales from its U.S. sales database in accordance with the CAFC's ruling in *NSK.* SNR France states that it responded to the Department's questionnaire regarding sample sales fully and the Department did not ask additional questions in its supplemental questionnaire.

Torrington responds that the Department must first determine whether a respondent has answered the Department's questions regarding sample sales at a sufficient level and a deficiency in this regard should draw an appropriate adverse inference. Torrington contends that the Department should assume that withheld information would have established that consideration (to which the court referred in *NSK*) was provided. Torrington maintains that such a fact pattern exists for SNR France and the Department should make an adverse inference. Torrington points to SNR France's questionnaire response wherein it declined to answer questions regarding sample sales.

Department's Position: We agree with SNR France. The firm provided a basic description of the sample sales it reported for the review period. Moreover, we found no evidence on the record that SNR France received consideration for reported U.S. sample transactions. Therefore, for these final results, we have excluded these sales from the U.S. sales database.

Comment 6: Torrington argues that the Department should reject SKF Germany's claims that sales identified as samples or prototypes should be excluded from the HM sales database because SKF Germany did not supply much of the information the Department required to support exclusion. In arguing that the respondent has the burden of proof when claiming favorable adjustments, Torrington cites *Fujitsu General Limited* v. *United States,* 88 F.3d 1034, 1040 (CAFC 1996). Torrington adds that the Department denied such claims with regard to SKF and NTN in the 1994/95 reviews.

SKF Germany argues that its response regarding samples and prototypes should be sufficient to justify SKF Germany's claim for exclusion of these transactions from its HM database. SKF Germany explains that there were few transactions involving samples and prototypes in the HM, thereby not warranting the expenditure of the substantial resources needed to provide the detailed data responsive to the Department's request.

Department's Position: We agree with SKF Germany. SKF Germany provided a basic description of the sample and prototype sales it reported for the review period. Moreover, we found no evidence on the record that SKF Germany received consideration for reported HM sample and prototype transactions. Therefore, for these final results, we have excluded these sales from the HM sales database.

Comment 7: INA asserts that the Department must exclude zero-priced samples given to customers at no charge from the U.S. sales database as these are not ''sales'' within the meaning of the antidumping law, citing *NSK.*

With regard to INA's zero-priced sample transactions, Torrington asks that the Department draw an adverse inference and not exclude any such transactions from the U.S. sales database. Torrington asserts that INA elected not to provide the information the Department requested and stated that it could not systematically identify sample transactions from its sales records.

Department's Position: We agree with Torrington. As we noted in the introduction to this issue, the party in possession of the information has the burden of producing that information, particularly when seeking a favorable adjustment or exclusion. INA did not answer our questions regarding the purchase history of parties receiving samples. INA also did not answer our questions regarding the prices and quantities involved in sample transactions. The answers to these questions would have aided us in determining whether INA received a bargained-for exchange from its U.S. customers. Lacking knowledge of the details of these transactions, we cannot conclude that INA received no consideration for these alleged samples. In other words, because INA impeded our investigation of these transactions, we determined that an adverse inference is appropriate. Therefore for these final results, we have included INA's sample sales in its U.S. sales database.

With regard to INA's HM ''zero-priced'' sample transactions, INA provided a complete response with respect to these transactions. We examined the record and found no evidence that INA received consideration for its HM sample transactions. Therefore, in accordance with the CAFC's decision in *NSK,* we have excluded INA's reported HM ''zero-priced'' sample transactions.

10. Export Price and Constructed Export Price

Comment 1: INA argues that the Department calculated CEP profit incorrectly on a class-or-kind basis. INA contends that the calculation should have been on a product-specific basis, since the Department makes the CEP-profit adjustment on a transaction-specific basis.

INA contends that section 772(d) of the Tariff Act provides that, in establishing CEP, the Department will make certain additional deductions beyond those it makes in establishing EP. According to INA, all of these deductions are transaction-specific since they are applied to a particular U.S. price and among the deductions is CEP profit, which is allocated to CEP expenses.

INA argues further that section 772(f) provides that the Department will determine the CEP-profit rate with reference to ''the expenses incurred with respect to the subject merchandise sold in the United States and the foreign like product sold in the exporting country.'' Therefore, INA argues, since the Department uses the profit rate to determine transaction-specific profit under section 772(d) and applies it to transaction-specific expenses, it is apparent that ''the subject merchandise sold in the United States'' in section 772(f) refers to the particular merchandise for which CEP profit is being calculated. Thus, INA claims the ''foreign like product'' must refer to merchandise in the same family as the U.S. merchandise.

Furthermore, INA argues that merchandise that may be a foreign like product with respect to one model sold in the United States may not be a foreign like product with respect to another.

Therefore, INA argues that it is logically impossible for an aggregation of like products to be ''the foreign like product'' to all subject merchandise.

Finally, INA argues that the expense and profit data necessary to calculate CEP profit for each bearing family is on the record and, therefore, the Department should calculate CEP profit on this basis, not on an aggregation of reported HM and U.S. data. In support of INA, SKF argues that calculating CEP profit on a product-specific basis would lead to more accurate results.

Torrington counters that the Department's methodology for calculating CEP profit on a class-or-kind basis is a reasonable application of the statute, citing section 772(e) and the SAA at 824–825. Torrington disagrees with INA and SKF by arguing that the statute does not require the Department to calculate CEP profit on a product-specific basis and that, where the statute is silent or ambiguous with respect to a specific issue, the agency's methodology is permissible if based on a reasonable construction of the statute. Petitioner argues that the Department's methodology is reasonable and, therefore, is permissible.

Department's Position: We agree with Torrington. As discussed in more detail in *AFBs VI,* neither the statute nor the SAA requires us to calculate CEP profit on bases more specific than the subject merchandise as a whole. *See AFBs VI,* 62 FR at 2125. Respondent's suggestion would add a layer of complexity to an already complicated exercise with no increase in accuracy. Furthermore, a subdivision of the CEP-profit calculation would be more susceptible to manipulation.

Comment 2: SNR France and INA Germany argue that the Department excluded imputed expenses (credit expenses and inventory carrying costs) erroneously from its calculation of CEP profit, yet it applied the resulting profit factor to a U.S. selling expense total that includes these imputed costs. This, SNR France and INA Germany maintain, results in an unfair adjustment to U.S. price.

Torrington argues that this methodology conforms with the Department's practice in the 1994/95 reviews. Torrington suggests that the Department reject SNR France's and INA Germany's arguments for the reasons in *AFBs VI* at 2126.

Department's Position: We agree with Torrington. SNR France's approach blurs the definition of U.S. expenses, as defined in section 772(f)(2)(B), and U.S. selling expenses, as defined in section 772(d) (1) and (2). As we discussed in *AFBs VI,* 62 FR at 2126, sections 772(f) (1) and 772(f)(2)(D) of the Tariff Act state that the per-unit profit amount shall be an amount determined by multiplying the total actual profit by the applicable percentage (ratio of total U.S. expenses to total expenses) and that the total actual profit means the total profit earned by the foreign producer, exporter, and affiliated parties. In accordance with the statute, we base the calculation of the total actual profit used in calculating the per-unit profit amount for CEP sales on actual revenues and expenses recognized by the company. In calculating the per-unit cost of the U.S. sales, we have included net interest expense. Therefore, we do not need to include imputed interest expenses in the ''total actual profit'' calculation since we have already accounted for actual interest in computing this amount under section 772(f)(1). When we allocated a portion of the actual profit to each CEP sale, we have included imputed credit and inventory carrying costs as part of the total U.S. expense allocation factor. This methodology is consistent with section 772(f)(1) of the statute, which defines ''total United States Expense'' as the total expenses described under sections 772(d) (1) and (2). Such expenses include both imputed credit and inventory carrying costs. *See Certain Stainless Wire Rods from France,* 61 FR 47874, 47882 (September 11, 1996).

Comment 3: Torrington alleges that NTN failed to include certain expenses incurred in the United States within the NTN organizational structure as CEP selling expenses. In rebuttal, NTN argues that the Department asked NTN the exact question that Torrington now raises and accepted NTN's response appropriately.

Department's Position: We agree with NTN. Because of the proprietary nature of the comments we received on this issue, however, we are not able to respond adequately in this notice. *See* proprietary memorandum to the file dated September 22, 1997.

Comment 4: Torrington alleges that certain of NTN's claimed EP transactions are actually CEP transactions when examined in light of the criteria for defining EP transactions as outlined in the Department's *Antidumping Manual.* Petitioner notes that these criteria are (1) the sales transaction occurs prior to importation; (2) the merchandise in question was shipped directly from the manufacturer to the unrelated buyer, without being introduced into the inventory of the related selling agent; (3) this was a customary commercial channel for sales of this merchandise between the parties involved; and (4) the related agent in the United States acted only as a processor of the sales-related documentation and a communication link with the unrelated U.S. buyer. Citing to *Certain Cold-Rolled and Corrosion-Resistant Carbon Steel Flat Products from Korea,* 62 FR 18,404 (April 15, 1997)(*Steel*), petitioner contends that, when the activities of the related selling agent exceed the functions normally associated with a related agent involved with EP sales, this indicates that the related agent is involved in more than just EP sales. Petitioner cites the following passage from the Department's *Antidumping Manual* (1994) as examples of selling activities that exceed those associated with EP sales:

> The extent of the related selling agent's normal functions, such as the administration of warranties, advertising, extensive in-house technical assistance, and the supervision of further manufacturing, may indicate that the agent is more than the ''paper-pusher'' envisioned for purchase price sales. *Id.* chapter 7 at 4–5.

Torrington concludes that this is the case for the sales in question and that they should be reclassified as CEP transactions.

In response, NTN argues that *Steel* provides no support for its position since it involved instances where there was a sale by the affiliated U.S. importer. NTN states that the Department verified the sales in question and found them to be sales by NTN Japan to an unaffiliated customer in the United States. NTN argues that for the petitioner to contend that such sales are CEP sales ignores the verification findings and effectively creates a sale between the unaffiliated customer and a NTN U.S. subsidiary (NBCA) where there were no sales negotiations between the unaffiliated customer and NBCA, no purchase orders from the unaffiliated customer, no invoices from NBCA, NBCA never takes title to the merchandise, NBCA never carries the merchandise in its inventory, and NBCA never acts as the importer of record. In summary, NTN states that these sales were made in Japan and met the Department's definition of EP sales transactions and that its affiliated party in the United States performed no activities other than those of being a communications link or processor of documents. Finally, NTN argues that it provided further information in response to a supplemental questionnaire and that the Department accepted this information.

Department's Position: We agree with NTN. Torrington lists the criteria the Department considers when deciding whether sales should be classified as EP or CEP. Of the criteria outlined, however, the only area that Torrington questions is the activities of NBCA's liaison office. As NTN notes, there is no information on the record suggesting that NBCA is the seller for the sales in question or that NTN has otherwise misreported the sales. Moreover, although we did not verify NTN's response for these reviews, we have verified this issue in past reviews and found no activities related to these sales. Therefore, after examining documentation for sales to the customer

in question, concluded that they were categorized properly as EP transactions. Inasmuch as nothing on the record indicates any change in NTN's business practices, we determine these sales to be EP transactions.

Comment 5: NTN argues that the Department should calculate CEP profit on a level-of-trade-specific basis. NTN maintains that the statute expresses a preference for CEP profit to be calculated on the narrowest possible basis which, NTN states, ensures more accurate results, citing section 772f(2)C)(ii). NTN argues that, in accordance with the statute and for the purpose of employing as specific and accurate expenses as is possible in the calculation of NV and CEP, the Department accepted NTN's reported level-of-trade-based selling expenses and should, for the same reasons, calculate CEP profit based on level of trade such that it accounts for price differences at the levels.

Torrington contends that sections 772(C) and (D) of the statute requires that total expenses and profit be reported, not level-of-trade-specific expenses and profit. Torrington maintains further that, as the Department stated in the preamble to its new regulations, CEP profit should be based on all sales and anything less would further complicate the calculation and make the Department more vulnerable to manipulation.

Department's Position: We agree with Torrington for the reasons we discussed in response to comment 1 above and in *AFBs VI*, 62 FR at 2125.

11. Programming and Clerical Errors

FAG Germany, INA, Koyo, Nachi, NPBS, NTN Japan, SKF Italy, SKF Germany, SKF France, SKF Sweden, SNR France, and Torrington made allegations of programming or clerical errors. Where all parties and we agree that a programming or clerical error occurred, we made the necessary correction and addressed the comment in the final results analysis memoranda. The comments we included here address situations where parties alleged that we made a programming or clerical error but either we or another party to the proceedings disagrees with the allegation. This section of the notice also deals with clerical errors that respondents made but did not bring to our attention until after issuance of the preliminary results.

Comment 1: Nachi contends that, due to a programming error, the Department's credit-period calculation improperly inflates imputed credit expenses for U.S. sales. (The reason for this error is proprietary; therefore, we are not able to include a summary in this notice. For a detailed description of the error, please see page 3 of Nachi's July 1, 1997, Japan Issues Case Brief.) Nachi provides programming language intended to correct this error.

Instead of making the programming correction Nachi requested, Torrington requests a methodological change. Citing the questionnaire and the antidumping manual, Torrington asserts that the Department should base imputed credit expense solely upon the short-term interest rate of the U.S. affiliate. Torrington argues that the credit terms offered to the U.S. affiliate by the foreign exporter do not provide a basis to recalculate part of the U.S. credit expense. Torrington argues further that, if the Department accepts Nachi's methodology for calculating credit expense, the Department should not correct the programming error by using the computer language Nachi presented. Torrington contends that Nachi's suggested computer language is flawed.

Department's Position: We agree with Nachi that the credit-period calculation contains a programming error that inflates the imputed credit expense for U.S. sales improperly. As described below, we corrected the programming error using the programming language Torrington suggested on page 4 of its July 8, 1997, Japan Issues Rebuttal Brief.

We disagree with Torrington's allegation that Nachi's credit-expense calculation methodology is improper. The foreign parent has to finance its receivables using short-term loans during the period in which its U.S. affiliate has not paid for purchases from the foreign parent. Only after the U.S. affiliate reimburses its parent does it absorb the cost of purchasing the merchandise and thus have to begin to finance its own receivables. Therefore, we have accepted Nachi's U.S. credit expense methodology.

We agree with Torrington, however, that Nachi's suggested computer language is flawed as Torrington describes in its rebuttal brief. After analyzing the programming language Nachi suggested and the language Torrington suggested, we conclude that Torrington's language calculates credit expense as we intended for the preliminary results. Therefore, we have adopted Torrington's suggested programming language to account for the programming error Nachi alleged.

Comment 2: Torrington contends that an error occurred in the cost-test section of the Department's computer program for Barden. Torrington claims that the program should have identified as below-cost sales several observations that it treated as above cost.

Barden asserts that Torrington neither offers an explanation of how or why this alleged error occurred nor does Torrington offer computer language to correct it. Barden claims that it re-ran the computer program and found no discrepancies with this portion of the program. Barden requests that the Department therefore dismiss Torrington's argument.

Barden also argues that the Department had no legal or factual authority upon which to apply the below-cost test to its HM database. Barden asserts that the Department unlawfully disregarded below-cost sales in a previous review covering the 1993/94 period. Therefore, according to Barden, there is no lawful basis for the Department to request or utilize Barden's COP data in this review. Thus, Barden requests that the Department not apply a below-cost test to Barden's HM sales.

Department's Position: We disagree with Torrington. We have confirmed that the cost test is working properly. Specifically, it is disregarding individual below-cost sales where more than 20 percent of the quantity of sales of a model are below cost. Therefore, we have determined that the error Torrington alleged does not exist.

With respect to our application of the cost test to Barden's HM sales, we disagree with Barden. As we stated in *AFBs V* at 66490, we cannot disregard the fact that we found that Barden was selling its products below the COP in the HM. Therefore, we are required to disregard such sales in accordance with section 773(b) of the Tariff Act. Moreover, pursuant to our *AFBs V* determination of below-cost sales by Barden in the HM, in accordance with section 773(b)(2)(A)(i) of the Tariff Act, we have the authority in this review to request COP information and apply the cost test. As a result of applying the cost test, we found below-cost sales and, therefore, disregarded Barden's below-cost sales in accordance with the statute.

Comment 3: SNR France contends that it reported an incorrect adjustment for one of the U.S. sales transactions that the Department used for the antidumping margin calculations. SNR France explains that it should have reported a quantity adjustment but that instead it reported a billing adjustment equal to an amount of the gross unit price. SNR France requests that the Department review its submission dated June 19, 1997, and correct the error accordingly.

Department's Position: We established our criteria for the correction of clerical errors made by a respondent but discovered after the preliminary results in *Certain Fresh Cut Flowers from Colombia,* 61 FR 42833, 42834 (August 19, 1996) (*Flowers from Colombia*). In *Flowers from Colombia,* we stated that we will correct these types of errors under the following conditions: (1) The error in question must be demonstrated to be a clerical error, not a methodological error, an error in judgment, or a substantive error; (2) we must be satisfied that the corrective documentation provided in support of the clerical-error allegation is reliable; (3) the respondent must have availed itself of the earliest reasonable opportunity to correct the error; (4) the clerical-error allegation, and any corrective documentation, must be submitted to us no later than the due date for the respondent's administrative case brief; (5) the clerical error must not entail a substantial revision of the response; and (6) the respondent's corrective documentation must not contradict information previously determined to be accurate at verification.

SNR France has satisfied the Department's criteria for the correction of clerical errors made by a respondent but discovered after the preliminary results. Thus, we made the requested correction.

Comment 4: NPBS contends that, when testing prices to affiliated customers, the Department's computer program mistakenly treats sales to one customer as if they were sales to several different customers. NPBS explains that it assigned a different customer code for each of the customer's sales offices and the sales offices of the customer's sales subsidiary affiliate. NPBS requests that the Department rerun the arm's-length test, treating the separate codes as a single customer. NPBS also contends that, in the Department's arm's-length test, two of the customer codes used for identifying sales to the affiliated customer apply to different customers. NPBS states that the two customer codes identify unaffiliated customers that have the same first word in their names as the customer the Department intended to treat as an affiliate. NPBS argues that the customers in question have no affiliation with NPBS or the customer which the Department intended to treat as an affiliate.

Torrington contends that the Department has no obligation to comply with NPBS's request to rerun the arm's-length test and treat the separate codes as one customer. Torrington argues that NPBS has not alleged a clerical error in the application of the test but is taking issue with how the Department applied the test. Torrington asserts that the Department should make no change since NPBS has not explained why its methodology is better than the Department's.

Department's Position: We agree with respondent. NPBS is correct that we mistakenly treated sales to one customer as if they were sales to several different customers. For the arm's-length test, it was our intent to analyze the transactions as sales to a single customer. We have corrected this clerical error by assigning the affiliated customer a single code.

We also agree with NPBS that we should treat two of the customers we treated as affiliated in our preliminary results as unaffiliated. This clerical error occurred when we inadvertently assigned the customers the affiliation code because they have the same first word in their name as the affiliated customer. To correct the problem, we have conducted the arm's-length test without designating the two companies as affiliates.

Comment 5: Torrington contends that there is a programming error in the section of the Department's computer program for SKF France that converts expenses incurred in French francs on U.S. sales to U.S. dollars. To correct this problem, Torrington requests that the Department insert an ''ELSE'' statement in the line of programming that performs the exchange-rate conversion.

Department's Position: We disagree with Torrington. In the programming language to which Torrington refers, no ''ELSE'' statement is necessary. In SAS programming, an ''ELSE'' statement gives an alternative action if the ''THEN'' clause in an ''IF-THEN'' statement is not executed. In the section of SKF France's program to which Torrington refers, when the original ''IF'' clause is executed (*i.e.*, SKF France has reported no expense for the transaction), then the program simply multiplies the exchange rate by zero. If SKF France has reported an expense, then the program multiplies the exchange rate properly by the reported expense denominated in French francs. Torrington's suggested language will only result in the conversion being executed when an expense is missing and has been designated as zero. Because Torrington's suggested language does not affect the outcome of the programming instruction, we did not make the change.

Comment 6: NSK Japan argues that certain U.S. sales receiving facts available should be deleted from the Department's antidumping analysis. NSK Japan asserts that these sales were inadvertently included in the database due to a programming error on its part.

Department's Position: We agree with NSK Japan and have deleted these sales from our analysis for these final results. Though the proprietary nature of the comment prevents a full discussion here, we note that the accuracy of NSK Japan's assertion in its July 1, 1997, Japan Issues Case Brief is obvious from the record. Thus, NSK Japan has satisfied the Department's criteria for the correction of clerical errors made by a respondent but discovered after the preliminary results. *See Flowers from Colombia* at 42834 and our response to Comment 3 of this section.

Comment 7: Torrington argues that, when calculating NTN Japan's margin, the Department should assign a facts-available rate to certain HM transactions that lack a corresponding price. Torrington claims that the Department neglected to use these transactions in the preliminary margin calculations.

Department Position: Torrington has misinterpreted the results of our preliminary analysis. We have not applied facts available to these transactions. Due to the proprietary nature of the information, this issue is discussed further in the analysis memorandum (*see* NTN's analysis memorandum dated September 22, 1997).

12. Duty Absorption

Section 751(a)(4) of the Tariff Act provides for the Department, if requested, to determine whether antidumping duties have been absorbed by a foreign producer or exporter subject to the order if the subject merchandise is sold in the United States through an importer who is affiliated with such foreign producer or exporter. Section 751(a)(4) authorizes this type of investigation during an administrative review initiated two years or four years after publication of an order.

For transition orders as defined in section 751(c)(6)(C) of the Tariff Act (*i.e.*, orders in effect as of January 1, 1995), section 351.213(j)(2) of the Department's antidumping regulations provides that the Department will make a duty-absorption determination, if requested, for any administrative review initiated in 1996 or 1998. *See* 62 FR 27296, 27394 (May 19, 1997). Although these antidumping regulations are not binding upon the Department for these AFB reviews, they do constitute a public statement of how the Department expects to proceed in construing section 751(a)(4) of the Tariff Act. This approach ensures that interested parties will have the opportunity to request a

duty-absorption determination prior to the time of the sunset review of the order under section 751(c) on entries for which the second and fourth years following an order have already passed. Because these orders on AFBs have been in effect since 1989, these are transition orders in accordance with section 751(c)(6)(C) of the Tariff Act; therefore, based on the policy stated above, the Department will consider a request for an absorption determination during a review initiated in 1996 or 1998. On May 31, 1996 and July 9, 1996, Torrington requested the Department to determine, with respect to various respondents, whether antidumping duties had been absorbed during the POR. These being reviews initiated in 1996 and a request having been made, we have made a duty-absorption determination as part of these administrative reviews.

In our preliminary results of review, we calculated the percentage of sales by a U.S. affiliate with dumping margins for each exporter. We stated that, with respect to those companies (with affiliated importer(s)) that had dumping margins, we would rebuttably presume that the duties will be absorbed for those sales which were dumped. Subsequent to the preliminary results, we received comments.

Comment 1: Respondents claim that the Department has interpreted section 351.213(j) of its regulations incorrectly as providing for duty-absorption inquiries in the second and fourth years following a sunset review after which an order is continued and in periods such as the seventh and ninth reviews for transition orders. Citing the principle of statutory construction ''*expressio unius est exclusio alterius*,'' wherein there is an inference that all omissions should be understood as exclusions, respondents conclude that the lack of explicit Congressional approval for duty-absorption inquiries for the latter transition orders shows that Congress did not intend for duty-absorption inquiries to be initiated more than four years after publication of an antidumping order. Finally, respondents contend that the Department is incorrect in justifying the duty-absorption inquiry by calling AFBs orders transition orders in accordance with section 751(c)(6)(C) of the Tariff Act. According to respondents, section 751(c)(6)(C) of the Tariff Act only applies to ''sunset'' reviews.

Torrington claims that narrowing the applicability of the duty-absorption inquiries to only the second and fourth years of sunset reviews would unduly limit the effectiveness of the statute. Torrington claims that there is no indication that sections 751(a)(4) or 751(c)(6)(D) intended to create such a narrow application. Torrington's response to the legal principle of ''all omissions should be understood as exclusions'' is that it has little force in the administrative setting because deference is granted to an agency's interpretation of a statute, unless Congress has directly spoken to the question at issue (citing *Mobile Communications Corp. Of America* v. *F.C.C.*, 77 F.3d 1399, 1404–1045). Torrington further argues that ''whether the specification of one matter means the exclusion of another is a matter of legislative intent for which one must look at the statute as a whole'' (citing *Massachusetts Trustees of Eastern Gas & Fuel Associates* v. *United States*, 312 F.2d 214,220 (1st Cir. 1963) (citing authority), *aff'd*, 377 U.S. 235 (1964)).

Department's Position: With regard to the time frame in which we are conducting these reviews, section 351.213(j)(1), in accordance with section 751(a)(4), provides for the conduct, upon request, of absorption inquiries in reviews initiated two and four years after the publication of an antidumping order. The preamble to the proposed antidumping regulations explains that reviews initiated in 1996 will be considered initiated in the second year and reviews initiated in 1998 will be considered initiated in the fourth year (61 FR at 7317). Because these orders on AFBs have been in effect since 1989, these are transition orders in accordance with section 751(c)(6)(C) of the Tariff Act. This being a review initiated in 1996 and a request having been made, we are making duty-absorption determinations as part of these administrative reviews.

Comment 2: Respondents state that gauging absorption on information that they do not know until completion of an administrative review is unfair. More specifically, they claim that the nature of the review process prevents them from determining the U.S. price increase necessary to pass dumping duties onto customers because the ultimate liability is not determined until the end of a review. Respondents claim further that, other than dumping duties paid at the time of entry, they have no means of estimating the price increases necessary to pass dumping duties to the customers.

Finally, respondents argue that the Department cannot presume ''rebuttably'' that duty absorption on sales to the U.S. affiliate exists if the record does not contain evidence of the U.S. purchaser's assumption of liability for ultimate assessment. Respondents claim that the Department's rebuttable presumption ignores commercial reality in that no U.S. buyer would agree to assume liability for an unascertainable amount of duties. Respondents claim that the Department has not provided any reason for adopting the presumption of duty absorption and that the presumption is not allowable by law, citing *NLRB* v. *Baptist Hosp. Inc.*, 442 U.S. 773, 787 (1979), and *United Scenic Artists, Local 829* v. *NLRB*, 762 F.2d 1027, 1034 (D.C. Cir 1985).

SNR and SKF state that the 15-day deadline for submitting evidence to rebut the assumption that unaffiliated U.S. purchasers will pay the assessed dumping duty is too short, given the amount of evidence that would have to be collected and the number of customers that would have to be approached.

Finally, FAG Germany and FAG Italy contend that the duty-absorption inquiry is only applicable to the foreign producer or exporter, citing section 751(a)(4) of the Tariff Act.

Torrington agrees with the Department's approach in using the rebuttable presumption that the duties for sales that were dumped will be absorbed. Torrington argues that the Department's examination of whether duty absorption occurred by reviewing data on the volume of dumped imports and dumping margins follows the guidelines of the SAA. Torrington argues that the Department's decision was reasonable, given the lack of record evidence that the first unrelated customer will be responsible for paying the duty that is ultimately assessed and the consistency of the Department's dumping determinations and the fact that the Department gives the respondents the opportunity to provide evidence that the unaffiliated purchasers will pay the assessed duty. Additionally, Torrington asks that the Department reject respondents' inference that the absorption inquiry only extends to the foreign producer, rather than the foreign producer and affiliated importer(s). Torrington cites the preamble to the new regulations and the SAA at 885 in support of the latter.

Finally, Torrington claims that, while the difficulty of obtaining evidence increases with the extent of dumping involved, this does not mitigate against the Department's 15-day deadline (after the publication of preliminary results) for submitting evidence that unaffiliated U.S. purchasers will pay the assessed dumping duty.

Department's Position: We agree with Torrington. An investigation as to whether there is duty absorption does not simply involve publishing the margin in the final results of review. As

the Department noted in the preliminary results of these reviews, the determination that duty absorption exists is also based on the lack of any information on the record that the first unaffiliated customer will be responsible for paying the duty that is ultimately assessed. Absent such an irrevocable agreement between the affiliated U.S. importer(s) and the first unaffiliated customer, there is no basis for the Department to conclude that the duty attributable to the margin is not being absorbed.

This is an instance where the existence of a margin raises an initial presumption that the respondent and its affiliated importer(s) are absorbing the duty. As such, the burden of producing evidence to the contrary shifts to the respondent. *See Creswell Trading Co., Inc.* v. *United States,* 15 F.3d 1054 (CAFC 1994). Here, the respondents have failed to place evidence on the record, despite being given ample time to do so, in support of their position that they and their affiliated importer(s) are not absorbing the duties.

Comment 3: Torrington argues that, even though the Department's duty-absorption methodology is reasonable because it relies on a weighted-average dumping margin which takes all dumped sales into account, a more accurate reflection of the impact of dumping on the domestic industry could be achieved by taking weighted-average dumping margins divided by the percentage of the U.S. affiliate's sales with dumping margins. Torrington also contends that the proposal made by several respondents of taking into account negative margins masks dumping and contributes to an importer's financial ability to continue the practice of duty absorption.

Respondents contend that, once an importer has certified that it has not been reimbursed for antidumping duties, it is unnecessary for the Department to conduct a duty-absorption inquiry unless there is evidence of fraud. Respondents also emphasize that, if such weighted-average dumping margins were calculated, they could be highly distortive when applied to a small volume of transactions. Respondents claim further that, if the total profits exceed the amount of antidumping liability, this can be taken as proof that duty absorption is not occurring. SKF argues that, using data already available on the record, the Department is able to conduct an accurate analysis of whether dumping duties are being absorbed by comparing the total profit of CEP sales to the total amount of the antidumping liability. SKF also emphasizes that, while dumping must be measured on a transaction-specific basis, there are no reasons why a duty-absorption inquiry can not be done on an aggregate basis.

SKF, Koyo, NSK, and SNR argue that the Department's duty-absorption methodology fails to measure duty absorption on respondents' U.S. sales database as a whole. Respondents claim that by not considering sales made at non-dumped prices the Department fails to get an accurate measure of whether absorption has occurred. SKF and SNR emphasize that, because the Department calculates dumping margins after U.S. sales are shipped and invoiced, companies cannot calculate precisely the price necessary to eliminate dumping. Therefore, respondents assert they can only be expected to reach non-dumping price levels on an overall basis. As a result, SKF contends that the Department should use weighted-average margins which exclude from the percentage of dumped sales those transactions with *de minimis* margins as a threshold test for duty-absorption inquiries.

Department's Position: We disagree with respondents that we should aggregate negative and positive margins in our duty-absorption determination. The Department treats so-called ''negative'' margins as being equal to zero in calculating a weighted-average margin because otherwise exporters would be able to mask their dumped sales with non-dumped sales. *See Final Determination of Sales at Less Than Fair Value; Professional Electric Cutting Tools and Professional Electric Sanding/Grinding Tools from Japan,* 58 FR 30149 (May 26, 1993). It would be inconsistent on one hand to calculate margins using only positive-margin sales, which is the Department's practice, and then argue, in effect, that there are no margins for duty-absorption purposes because a deduction from the total duties determined should be made for sales without margins. *See Certain Hot-Rolled Lead and Bismuth Carbon Steel Products From the United Kingdom; Final Results of Antidumping Duty Administrative Review,* 62 FR 18744, 18745 (April 17, 1997). However, non-dumped sales affect the percentage of sales through affiliated importers which are dumped and therefore affect the results of the absorption inquiry. Therefore, we disagree with Torrington's suggestion as well. Only using the sales with dumping margins in the denominator of our calculations would distort the calculations by overstating the percentage margin of dumping.

Finally, a company's profit on CEP sales is not a relevant issue. This, too, does not negate the fact that these are duties absorbed by the affiliate.

13. Reimbursement

Comment 1: Torrington states that the Department should apply the reimbursement regulation in situations where the transfer prices to an affiliated importer are below the actual COP and the transactions were found to have dumping margins. Torrington contends that below-cost transfer prices are tantamount to an indirect transfer of funds, allowing ''foreign deep pockets'' to relieve importers from having to raise resale prices to finance assessment of antidumping duties. Torrington, citing *Color Television Receivers from Korea,* 61 FR 4408, 4411(Feb. 6, 1996), states further that, because the Department concluded that the reimbursement regulation applies in exporter's-sales-price situations, the Department should apply the reimbursement rule to indirect payments between affiliated parties in these reviews. Finally, Torrington states that the Department should ask each respondent whether it transferred subject merchandise to its affiliated U.S. importer at prices below the COP and whether it made any capital, equity or other contributions to its U.S. affiliate during the POR.

Respondents state that when deciding this issue the Department should maintain its reliance, as it did during the 1992/93, 1993/94, and 1994/95 reviews, on whether explicit and specific factual evidence exists of direct reimbursement of dumping duties by an affiliated importer. Koyo, NSK, INA, and SNR state that Torrington's allegations of below-cost transfer prices do not establish the specific and direct links between transfer pricing and reimbursement, cited in *Federal-Mogul Corp* v. *United States,* 918 F.Supp. 386, 394 (CIT 1996)(*Federal-Mogul I*), necessary to conclude reimbursement has occurred. Koyo further states that the *Korean TVs* case does not undermine the CIT's decision in *Federal-Mogul I,* or the Department's refusal to undertake reimbursement investigations in the last four AFBs reviews, simply on the basis of below-cost transfer prices.

NTN cites the Department's revision of its regulations on antidumping and countervailing duties to conform with the URAA multilateral trade negotiations (62 FR 27355) as evidence that Congress has rejected the application of the reimbursement regulation (section 351.402(f) (1997)) to below-cost transfer pricing between affiliated parties. NTN claims that, when the express intent of Congress is unclear or ambiguous, deference will be

granted to the Department's interpretation of its own regulations and, therefore, the Department has been granted broad discretion in determining what constitutes reimbursement of antidumping duties for purposes of 19 CFR 353.26 (1996).

In response to Torrington's suggestion to pursue two additional lines of inquiry regarding reimbursement, NSK states that the Department should conclude reimbursement has occurred only when dumping duties are paid directly on behalf of the importer or when dumping duties are actually reimbursed to the importer. FAG Italy, NSK, Barden, and NTN state that, when certification of non-reimbursement is filed and there is no evidence of Customs fraud, the Department has no further obligation to investigate because there is no basis for presumption of reimbursement and no statutory authority to place any burden on respondents to rebut such a position. SKF Italy and Germany also note that their borrowing behavior is already addressed in their responses to the Department's questionnaire and that the Department verified this issue, eliminating the need to collect further data.

FAG Italy, SKF, Koyo and Nachi state that, despite having numerous chances to present new arguments or evidence to the Department, Torrington failed to offer anything that would warrant reconsideration of the Department's previous position.

Department's Position: We disagree with Torrington. Although we agree that the reimbursement regulation is applicable in CEP situations, there must be evidence that the parent has reimbursed (*e.g.*, the exporter directly paid the duties for the importer or the exporter lowered the amount invoiced to the importer) its subsidiary for antidumping duties to be assessed (*see Korean TVs* at 4410–11). In that case, we reaffirmed our original view that reimbursement, within the meaning of the regulation, takes place between affiliated parties if the evidence demonstrates that the exporter directly pays antidumping duties for the affiliated importer or reimburses the importer for such duties (*see The Torrington Company* v. *United States*, Slip Op. 97–136 (CIT September 19, 1997)(*Torrington II*)). In this case, there is no evidence that any of the named respondents engaged in reimbursement activity with their respective affiliated U.S. subsidiary. *See also Brass Sheet and Strip from the Netherlands*, 57 FR 9534, 9537 (March 19, 1992), *Brass Sheet and Strip from Sweden*, 57 FR 2706, 2708 (January 23, 1992), and *Brass Sheet and Strip from Korea*, 54 FR 33257, 33258 (August 14, 1989).

Furthermore, Torrington has presented no evidence of inappropriate financial intermingling, an agreement to reimburse, or reimbursement in general. FAG, Koyo, and Nachi are correct in that the presence of both below-cost transfer prices and actual dumping margins do not, in and of themselves, constitute evidence that reimbursement is taking place. Therefore, consistent with our position in previous reviews of these orders, we reject Torrington's contention that below-cost transfer prices are tantamount to an indirect transfer of funds for reimbursement of antidumping duties and that we should make a deduction therefore in CEP transactions (*see AFBs III* (39736), *AFBs IV* (10906–07), *AFBs V* (66519), and *AFBs VI* (2129)).

14. Tooling Revenue

Comment: NSK argues that the Department should not consider tooling to be part of revenue for the purpose of calculating the dumping margins. NSK claims that tooling revenue is not an integral part of the product, that the Department did not include this item in its questionnaire for previous reviews, and that Torrington did not consider tooling as part of revenue in past AFB reviews. NSK also cites the Department's position in *Mechanical Transfer Presses from Japan*, 55 FR 335, 339 (Jan. 4, 1990), where the Department did not adjust prices by an amount for tooling. Finally, NSK points out that, in situations where tooling can be considered subject merchandise, it is specifically identified as an integral component of the price, citing *Certain Forged Steel Crankshafts from the United Kingdom*, 56 FR 5975, 5978 (Feb. 14, 1991).

NSK argues that, even if the Department maintains that tooling revenue should be added to NV, the Department should not add tooling revenue to NV as facts available in its analysis of NSK. NSK argues that it is inappropriate to use facts available in its case because it responded fully to all of the Department's requests for information. NSK argues that it provided tooling revenue on a product-specific basis and the fact that the Department could not match the tooling revenue to the product codes in its HM sales database demonstrates that those products to which it would apply were not reported in the database.

Torrington disagrees with NSK's position, claiming that the Department should include tooling revenue in the computation of NV pursuant to the terms of the antidumping duty order, the applicable law, and the questionnaire. Petitioner cites two cases where the Department ruled as such: *Certain Forged Steel Crankshafts From the United Kingdom*, 56 FR 5975, 5978 (Feb. 14, 1991), where tooling revenues were included in price even when tooling is billed separately, and *Bicycle Speedometers From Japan*, 58 FR 54328 (Oct. 21, 1993), where amortized tooling costs were added to, not subtracted from, price. Torrington claims that the supplemental questionnaire in these AFB reviews further demonstrates the Department's policy of including tooling in revenue since it asks for detailed information on tooling costs. Finally, Torrington states that tooling is a cost of producing bearings and that, in all market-type transactions, prices are set to cover costs.

Department's Position: In the *Final Determination of Sales at Less Than Fair Value: Oscillating Fans From the People's Republic of China*, 56 FR 55271, 55279 (Oct. 25, 1991), the Department established its policy of considering tooling as part of factory overhead and, therefore, a component of final price. The Department has followed this practice in subsequent cases. *See, e.g., Certain Forged Steel Crankshafts from the United Kingdom, 55 FR at 5978, and Bicycle Speedometers from Japan*, 58 FR at 54328. In *Mechanical Transfer Presses from Japan*, 55 FR at 339, the Department disallowed die tooling from revenue computation because it was identified separately in the contractual sales documentation along with spare parts and other optional item prices and, therefore, was not an ''integral'' cost of the commodity. In contrast, tooling revenue associated with AFBs is additional revenue on the sale of the AFB, not a separate accessory.

However, upon re-examining the record, we determine that it is clear from the record that NSK's reported tooling revenue pertains to models which NSK did not report, appropriately, in its HM sales database. Therefore, we have not added tooling revenue to NSK's NV for these final results. We note, however, that the application of facts available in our preliminary results was not meant to be a tool to punish NSK but rather to be an estimate of NSK's actual experience with regard to tooling revenue when we were unable to match the models for which tooling revenue was incurred to the models NSK reported in the HM sales database.

15. Cash Deposit Financing

Comment: NTN and NTN Germany (collectively ''NTN'') argue that the

Department's decision to ignore adjustments to its U.S. indirect selling expenses for interest on cash deposits of antidumping duties is contrary to the Department's position in past reviews of these orders and in recent litigation.

NTN argues that section 772(d)(1) of the Tariff Act only allows for the deduction of selling expenses. However, NTN contends, the Department has previously stated that it does not consider cash deposit financing expenses as such. As an example, NTN contends, the Department noted in *AFBs VI* at 2,104 that such expenses were not selling expenses since they ''were incurred only because of the existence of the antidumping duty orders'' and the Department concluded that ''the expenses cannot correctly be characterized as selling expenses.'' NTN also points to the Department's acceptance of this adjustment in the first three reviews of these orders (*AFBs I-III*), in the two most recently completed reviews of these orders (*AFBs V and VI*), and in the position the Department took in comments it filed with the CIT in the litigation arising from AFBs IV. According to NTN, the CIT adopted these comments in large part, holding that ''interest NTN paid for antidumping duty deposits is not a selling expense and, thus, should be excluded from NTN's U.S. indirect selling expenses.'' *Federal-Mogul* v. *United States*, 20 CIT —, —, Slip Op. 96–193 (December 12, 1996) (*Federal-Mogul II*).

NTN argues that, notwithstanding Departmental and judicial precedent, the Department's statements in the instant review are flawed. First, NTN contends, the Department's statement in the preliminary results that it is ''not convinced that there are opportunity costs associated with paying deposits'' contradicts the well-reasoned analysis the Department set forth in *Tapered Roller Bearings and Parts Thereof, Finished and Unfinished, From Japan, and Tapered Roller Bearings, Four Inches or Less in Outside Diameter, and Components Thereof, From Japan; Final Results of Antidumping Duty Administrative Reviews and Termination in Part (TRBs Final Results*), 62 FR 11,825, 11828–830 (March 13, 1997), in which the Department explained that it ''recognize(s) that opportunity costs * * * have a real financial impact on the firm.''

Second, NTN argues, the Department misunderstands the basis for its allowance of the adjustment in prior reviews in its statement that ''the dumping margin should not vary depending on whether a party has funds available to pay cash deposits or requires additional funds in the form of loans.'' NTN agrees that this statement is correct but contends that this does not necessarily lead to the Department's preliminary conclusion that it should deny the adjustment. NTN points to *TRBs Final Results* where the Department reasoned that a firm may also choose to divert funds from other corporate activities to pay cash deposits but the opportunity costs associated with the diversion reflect a real cost to the firm.

Third, NTN asserts, the Department's statements that opportunity costs are not associated with making cash deposits is a misunderstanding of the definition of ''opportunity costs.'' NTN argues that opportunity costs are ''the real economic loss which an entity experiences when it must forgo some other, more profitable use of its resources,'' citing *Cartersville Elevator, Inc.* v. *ICC*, 724 F. 2d 668, 670 (8th Cir. 1984), and *Mira* v. *Nuclear Measurements Corp.*, 107 F. 3d 466, 472 (7th Cir. 1997) (describing the diversion of funds from more profitable activity as ''the classic definition of opportunity costs''). NTN argues that the expense associated with making cash deposits fits these definitions. In NTN's view, the source of the funds does not determine whether this is an opportunity cost because, in either case, these funds cannot be put to a more profitable use.

NTN concludes that, since the only reference to this issue in these proceedings is a memorandum to the file regarding an ex parte meeting with the Torrington Company dated April 23, 1997, there is no change in fact pattern or the law which would compel such a sudden shift in the Department's position. Moreover, NTN argues that, at some point, the Department's prior decisions become case law, citing *Shikoku Chemicals* v. *United States*, 16 CIT 383, 388 (1992). NTN requests that the Department allow the adjustment to U.S. indirect selling expenses for the final results.

Torrington argues that the Department properly rejected an adjustment to NTN's U.S. selling expenses for cash deposit financing expenses. Torrington contends that there are both policy and legal reasons that support the Department's decision.

Torrington argues that the Department's previous policy actually encouraged dumping by allowing larger and larger adjustments to selling expenses as deposit rates increased. Torrington reasons that, the more a company dumps its merchandise in the United States, the larger the interest payments covering duty deposits will be. Torrington concludes that, as the interest expense becomes greater and greater, so does the offset to indirect selling expenses. Likewise, the smaller the offset, the lower the final dumping margin. Thus, Torrington contends the Department's old policy actually encourages dumping. Torrington suggests that this scenario will be exacerbated over time as interest expense accumulates and in any interest expenses the Department imputes. Torrington asserts that, if offsets become sufficiently large, dumping margins can disappear without any change in pricing behavior.

Moreover, if the Department only allows an adjustment for actual interest paid, Torrington asserts that the previous policy discriminates against importers who finance deposits with cash because these importers would not have any interest payments.

Torrington agrees with the Department's statements in the *Preliminary Results* questioning whether ''opportunity costs'' are actually incurred because, Torrington argues, ''opportunity costs'' exist only in economic theory. Torrington contends that, if deposits were not made, then there would be no merchandise to resell. Thus, Torrington concludes, deposits are a cost of doing business for those who choose to trade unfairly.

Torrington acknowledges that the CIT, in *Federal-Mogul II*, reached a contrary conclusion, but, petitioner contends the CIT upheld bad policy and the Department is right in changing its policy. Torrington argues that money is fungible and loans to finance duty deposits make money available for other endeavors. Torrington argues that the CIT, in *Federal-Mogul II*, failed to account for this.

Torrington argues that section 772(d)(1) mandates the deduction of certain selling expenses from CEP. Since imputed expenses do not appear on the company's books, Torrington contends that an offset to those selling expenses is contrary to law because it reduces a mandatory deduction improperly.

In addition, Torrington argues that, under the URAA, CEP is meant to be a proxy for an arm's-length price to an unaffiliated importer. As such, Torrington contends, selling expenses such as those incurred for financing cash deposits are related solely to the sale to the affiliated importer and are not related to the resale to the unaffiliated U.S. customer. Torrington contends that the Department's new regulations reflect the contemporaneous construction of the URAA as evidenced by the preamble statement: ''In these final regulations, we have clarified that the Secretary will deduct only expenses

associated with a sale to an unaffiliated customer in the United States.'' By the same logic, Torrington argues, credit costs imputed to the importer on account of duty deposits should not be added back to CEP because these costs will not be deducted from CEP in the first place.

Torrington argues that, although the Department's new regulations do not apply to the current review per se, the foregoing analysis reflects existing practice under the new law, citing *Extruded Rubber Thread from Malaysia*, 62 FR 33,588 at 33597–98 (June 20, 1997). In sum, Torrington maintains that antidumping cash deposits (and any credit expenses imputed to those deposits) do not represent activities of the importer in selling the merchandise in the U.S. market.

Finally, Torrington argues that there is no evidence that any affiliated importers actually obtained loans for the purpose of paying cash deposits. Therefore, Torrington contends, there is no evidence that imputed credit costs are ''specifically associated with economic activities in the United States,'' citing *Certain Internal-Combustion Industrial Forklift Trucks from Japan*, 62 FR 5592 at 5611 (February 6, 1997). Without evidence that credit costs were incurred, Torrington asserts there is no basis to conclude that any deductions from CEP on account of the importer's expenses included such costs in the first place. As such, Torrington concludes, there is no basis for NTN's claimed adjustment.

Department's Position: We agree with Torrington that we should deny an adjustment to NTN's U.S. indirect selling expenses for expenses which NTN claims are related to financing of cash deposits. However, we have not adopted Torrington's logic entirely.

The statute does not contain a precise definition of what constitutes a selling expense. Instead, Congress gave the administering authority discretion in this area. It is a matter of policy whether we consider there to be any financing expenses associated with cash deposits. We recognize that we have, to a limited extent, removed such expenses from indirect selling expenses for such financing expenses in past reviews of these orders. However, we have reconsidered our position on this matter and have now concluded that this practice is inappropriate.

We have long maintained, and continue to maintain, that antidumping duties, and cash deposits of antidumping duties, are not expenses that we should deduct from U.S. price. To do so would involve a circular logic that could result in an unending spiral of deductions for an amount that is intended to represent the actual offset for the dumping. *See, e.g., AFBs II.* We have also declined to deduct legal fees associated with participation in an antidumping case, reasoning that such expenses are incurred solely as a result of the existence of the antidumping duty order. *Id.* Underlying our logic in both these instances is an attempt to distinguish between business expenses that arise from economic activities in the United States and business expenses that are direct, inevitable consequences of the dumping order.

Financial expenses allegedly associated with cash deposits are not a direct, inevitable consequence of an antidumping order. As we stated in the preliminary results: ''money is fungible. If an importer acquires a loan to cover one operating cost, that may simply mean that it will not be necessary to borrow money to cover a different operating cost.'' *See Preliminary Results* at 31,569. Companies may choose to meet obligations for cash deposits in a variety of ways that rely on existing capital resources or that require raising new resources through debt or equity. For example, companies may choose to pay deposits by using cash on hand, obtaining loans, increasing sales revenues, or raising capital through the sale of equity shares. In fact, companies face these choices every day regarding all their expenses and financial obligations. There is nothing inevitable about a company having to finance cash deposits and there is no way for the Department to trace the motivation or use of such funds even if it were.

In a different context, we have made similar observations. For example, we stated that ''debt is fungible and corporations can shift debt and its related expenses toward or away from subsidiaries in order to manage profit'' (*see Ferrosilicon from Brazil*, 61 FR at 59412 (regarding whether the Department should allocate debt to specific divisions of a corporation)).

So, while under the statute we may allow a limited exemption from deductions from U.S. price for cash deposits themselves and legal fees associated with participation in dumping cases, we do not see a sound basis for extending this exemption to financing expenses allegedly associated with financing cash deposits. By the same token, for the reasons stated above, we would not allow an offset for financing the payment of legal fees associated with participation in a dumping case.

We see no merit to the argument that, since we do not deduct cash deposits from U.S. price, we should also not deduct financing expenses that are arbitrarily associated with cash deposits. To draw an analogy as to why this logic is flawed, we also do not deduct corporate taxes from U.S. price; however, we would not consider a reduction in selling expenses to reflect financing alleged to be associated with payment of such taxes.

Finally, we also determine that we should not use an imputed amount that would theoretically be associated with financing of cash deposits. As Torrington points out, there is no real opportunity cost associated with cash deposits when the paying of such deposits is a precondition for doing business in the United States. Like taxes, rent, and salaries, cash deposits are simply a financial obligation of doing business. Companies cannot choose not to pay cash deposits if they want to import nor can they dictate the terms, conditions, or timing of such payments. By contrast, we impute credit and inventory carrying costs when companies do not show an actual expense in their records because companies have it within their discretion to provide different payment terms to different customers and to hold different inventory balances for different markets. We impute costs in these circumstances as a means of comparing different conditions of sale in different markets. Thus, our policy on imputed expenses is consistent; under this policy, the imputation of financing costs to actual expenses is inappropriate.

16. Romania-Specific Issues

Comment 1: TIE contends that the Department should use the factory overhead, SG&A, and profit values of an Indonesian steel producer (Jaya Pari) placed on the record for the POR rather than rely upon the surrogate values obtained from a cable submitted by the U.S. embassy in Jakarta. TIE purports that the Jaya Pari data identifies how the overhead, SG&A, and profit values were derived, whereas the embassy cable does not reveal how these values were calculated and, thus, TIE cannot determine and comment on the accuracy and representativeness of such values. TIE recognizes that, although Jaya Pari is not a bearings producer, the Department has established a preference for use of publicly available information (PAI) over embassy cable data. TIE argues further that the embassy cable is nearly six years old, whereas Jaya Pari's data was derived from a 1995 financial statement, a source upon which the Department has relied in prior non-market-economy bearing reviews. In addition, TIE maintains that the SG&A rate in the embassy cable is

extraordinarily high and has significantly contributed to its dumping margin.

Torrington discusses several reasons as to why the Jaya Pari financial statement is inappropriate. Torrington asserts that Jaya Pari's financial statement is missing certain pages which may contain information relevant to assessing the validity of the document. Torrington argues that the 1995 financial statement TIE placed on the record does not contain the level of detail necessary to determine how certain values (in particular, materials and factory overhead) were calculated. Torrington contends further that the financial statement reflects a much higher raw-materials value than the overhead value and, thus, such figures may be disproportionately allocated because certain elements such as energy, electrodes, and rolls relative to steel manufacturing do not appear to be included in the overhead category.

Torrington argues that the embassy cable explains clearly how the overhead figure was derived and may need only an additional adjustment made for energy costs. Torrington maintains that the factory overhead and SG&A rates the Department employed in the preliminary margin calculations are understated because they did not take energy costs into account. Torrington asserts that the ratios the Department obtained from the embassy cable and used in the calculation of overhead and SG&A are less affected by the lapse of time as opposed to absolute figures which are found in the financial statement.

Department's Position: We agree with TIE. We have determined that the financial statement of Jaya Pari provides more appropriate surrogate information than the information in the cable from the U.S. embassy. In our hierarchy for selecting data for possible surrogate values, we prefer to use current, publicly available information. The cable which we used in the preliminary results is over five years old and therefore substantially less contemporaneous than the Jaya Pari information. Torrington's concern that certain pages are missing is irrelevant because the necessary pages, which show the overhead, SG&A and profit calculations as well as the explanatory notes, have been submitted. Additionally, the level of detail shown in the financial statements is greater than that of the cable. Finally, we cannot accept Torrington's contention that the financial statements have included certain elements relative to steel making incorrectly under ''raw materials'' rather than ''overhead.'' We have no factual basis for concluding that the raw-materials category is disproportionally high relative to the overhead category, and it also would be contrary to normal accounting procedures to place these elements—-energy, electrodes and rolls are the ones hypothesized by Torrington—under the category of ''raw materials.''

Comment 2: Torrington argues that, in the preliminary results of review, the Department published an incorrect value for TIE's dumping margin. Torrington suggests that, for the final results of review, the Department multiply by 100 the dumping margin published in the preliminary results of review in order to convert it properly to a percentage.

Department's Position: We agree with Torrington. In the preliminary results, we did not express the calculated margin as a percentage and, therefore, the published margin was understated. We have converted the margin to a percentage for the final results.

Comment 3: Torrington contends that the International Labor Office (ILO) costs the Department employed in the preliminary results of review are flawed for several reasons: (1) the wage rates used reflect only minimum wages in Indonesia and, thus, do not represent actual labor wage costs accurately; (2) the minimum wage rates do not include fringe benefits and, thus, such rates do not reflect labor rates accurately; and (3) certain information the Department used to value both direct and indirect labor pertain to the industries which have different international standard industrial classification (ISIC) codes than bearings. Torrington points out that the proper ISIC code for the products under review was determined in a prior segment of this proceeding. Torrington argues that, in the interest of the Department's desire to obtain actual, or as accurately as possible, Indonesian labor rates, the Department should use for the final results of review a particular table from the ILO *Yearbook of Labour Statistics* for 1994 instead of information from the *Special Supplement to the Bureau of Labor Statistics* used in the preliminary results. Torrington maintains that the ILO *Yearbook of Labour Statistics* contains actual wage rates and states that, because this document is based on the same year and serves as the same source of information from which the Department extrapolated the wage rates for the preliminary results of review, it should not constitute new information. Torrington argues further that using such information is consistent with the Department practice to use independent sources of information.

TIE contends that the information Torrington proposes that the Department use for the final results of review constitutes new information because it is untimely and has not been placed on the record previously. TIE also argues that, despite the fact that this information is new, it is a deficient source of information upon which to rely for the final results of review for the following reasons: (1) the data is more than two years older than that which the Department relied upon for the preliminary results of review and, thus, does not meet the Department's standard of using information that is most contemporaneous to the POR; (2) the wage rates employed in the preliminary results of review represent actual costs; (3) unskilled direct labor would be overstated because the data Torrington proposes includes salaried or skilled labor rates; and (4) the data Torrington proposes may be affected by time and, thus, it is likely that the data may have changed over the past five years.

Department's Position: Petitioner discusses the suitability of surrogate labor rates and has submitted information in its case brief recommending that the Department adjust the rates. TIE has pointed out that this information was not previously on the record and constitutes new information. The Department agrees with TIE that the labor rates which petitioner presents constitute new information. As such, we have not considered it, in accordance with 19 CFR 353.31(a), because it was submitted after the publication of the preliminary results and more than 180 days after the date of publication of the notice of initiation of this review.

We agree with TIE that the wage rates we used in the preliminary results represent actual costs. Although the ILO data is a minimum wage, it does indeed include such costs as ''cost-of-living allowances and other guaranteed and regularly paid allowances,'' according to the ILO's Special Supplement to the Bulletin of Labor statistics (1994). However, we agree with Torrington that the wage rates do not include fringe benefits. We have made an adjustment to the rates to include employee benefits, following the methodology in *Final Determination of Sales at Less than Fair Value; Disposable Pocket Lighters from the People's Republic of China,* 60 FR 22359 (May 5, 1995) (*Disposable Pocket Lighters*), which calculated supplementary benefits as 33 percent of manufacturing earnings. Finally, for indirect labor, rather than continue to use the rates for supervisors and general foremen from the crude

petroleum and natural gas industries, we have used the supervisory labor rates from *Disposable Pocket Lighters,* which we have inflated for the POR. This rate is not industry-specific but, rather, represents a general estimate of supervisory labor in Indonesia. It is more accurate than the crude rate for the petroleum and natural gas industries, which represents supervisory labor in an industry which is not representative of AFB production.

Comment 4: TIE contends that the foreign inland freight rate which the Department used in the preliminary margin calculations is extraordinarily high compared with the rates used in prior Romanian AFB and TRB reviews and rates used in a prior Chinese TRB review. TIE also argues that the proposed rate is also much higher than ocean freight, implying that it costs more to transport bearings within Romania than it costs to ship them from Romania to the United States. TIE maintains that the high inland freight rate is attributable to either a mathematical error in the Department's calculations or the estimated freight rate which incorporates a division of an arbitrary distance of 40 kilometers per trip and yields an estimated per kilometer rate. TIE provides a hypothetical example based on a 1500-kilometer distance between its factories and the port. TIE asserts that using this distance in the Department's calculation would yield a freight rate that is 20 percent of the sales value which, TIE claims, is overtly incorrect. TIE maintains that the Department has a long-established practice to ascertain whether surrogate values are reasonable and argues that, in the instant review, the Department should use a more reliable and reasonable rate for foreign inland freight.

Torrington contends that TIE did not attempt to substantiate that the foreign inland freight rate in the preliminary margin calculations was too high other than comparing that rate with rates used in other determinations. In addition, Torrington argues that TIE's hypothetical example is baseless because the actual distance between the factories and the port is under 400 kilometers. Torrington also contends that utilizing a distance of 1500 kilometers in the Department's calculation results in a percentage that is nowhere near 20 percent of the sales prices as claimed by TIE.

Department's Position: We agree with TIE. We have changed the truck freight rate for these final results. Because the freight-rate calculation includes a division by an estimated distance for the distance of transporting goods, we have determined that the resulting estimated rate is less accurate than the rate we used in *Disposable Pocket Lighters. See* Surrogate Freight submission, March 4, 1997. We consider the freight rate we applied in *Disposable Pocket Lighters* to be more accurate because it is based on actual data from a cable from the U.S. Embassy in Indonesia and does not contain an estimated component. Additionally, we have inflated the value using the World Price Index for the POR. Therefore, we have used the rate of $.0326 per MT/km for the truck freight rate for the final results.

17. Miscellaneous Issues

17. A Ocean & Air Freight

Comment: Torrington notes that the Department permitted respondents to aggregate and then allocate ocean and air freight costs. Torrington argues that this practice is potentially distortive because air freight is considerably more expensive on a per-unit basis. Torrington claims further that it is relatively easy to segregate air freight from ocean freight because the situations in which companies use air freight, such as emergencies and production scheduling, are easily identified. Torrington states that the Department should require respondents to submit information segregating air freight expenses or, absent such information, apply facts available.

FAG Germany, FAG Italy, NSK, SKF France, SKF Germany, SKF Italy, SKF Sweden, Koyo, NSK Japan, INA, Barden, and NMB/Pelmec contend that it is impractical and in some cases impossible to isolate air and ocean freight charges with their record-keeping systems. Respondents also assert that the Department verified their reported freight costs and found them to be non-distortive in these reviews or in prior reviews. NSK argues that it is unreasonable to have to resubmit freight charges at a late date. Koyo and NSK also contend that past administrative and legal procedures support the aggregation and allocation of freight costs, asserting that the Department in past reviews and the CIT in various decisions have both upheld their freight-reporting methodologies.

In addition, Barden contends that all of its U.S. freight charges were by air and reported as such, while NSK states that it kept records of ''expedited deliveries'' that could be tied to specific sales and reported such expenses separately.

Department's Position: We disagree with Torrington. We have found that it is generally not feasible for respondents to report air and ocean freight on a transaction-specific basis in these proceedings. *See, e.g.,* NSK's September 9, 1996 section C response at 22. Where respondents were unable to report ocean and air freight separately, we have accepted aggregated international freight data. *See AFBs VI,* 62 FR at 2121; *see also The Torrington Company* v. *United States,* Slip Op. 97–57 at 11–14 (CIT May 14, 1997)(*Torrington III*) (affirming the Department's methodology for accepting co-mingled ocean and air freight where a respondent could not report the two expenses separately). Furthermore, we note that § 351.401(g) of our new antidumping regulations provide that we may consider allocated expenses and price adjustments when transaction-specific reporting is not feasible, provided we are satisfied that the allocation method used does not cause inaccuracies or distortions. *See* 62 FR 27410 (May 19, 1997). As discussed above, the Department has determined that it is generally not feasible for respondents to report air and ocean freight on a transaction-specific basis.

Furthermore, while we have considered Torrington's claim that aggregating and then allocating air and ocean freight is ''potentially'' distortive, we have no evidence that this methodology in fact distorts respondents' reported freight costs. While the new regulations are not binding in the instant reviews, they are a codification of our intended practice.

Because we determined that respondents acted to the best of their ability, it would be improper to make adverse inferences about their reported data by applying facts available simply because their record-keeping systems do not record their data on a transaction-specific basis. Therefore, we have accepted respondents' reported air and ocean freight expenses.

17.B. Burden of Proof

Comment: Torrington argues that the Department has shifted the burden of proof improperly to petitioner to demonstrate the invalidity of respondents' claims. Torrington asserts that the Department's error originated in the 1994/95 reviews and was aggravated by the Department's refusal to require respondents to state when they have disregarded prior determinations and by the Department's acceptance of petitioner-challenged respondent data without Department verification. Torrington maintains that, when the Department found there to be no information demonstrating distortive allocations of post-sale price adjustments, it effectively shifted the burden of proof to petitioners to present information to refute respondents'

claims. Torrington argues that, since it has no right to conduct discovery or to attend verifications and since respondents possess all of the information relevant to distortion, respondents should bear the burden of proof regarding the distortion issue. Torrington asserts that *Fujitsu General Ltd.* v. *United States,* 88 F.3d 1034 (CAFC 1996), and *Timken Co.* v. *United States,* 673 F. Supp. 495 (CIT 1987), support its contention that respondents should bear the burden of demonstrating whether an allocation causes distortive results.

Torrington maintains that the Department shifts the burden of proof when it chooses not to verify and accepts respondents' data and when the Department does not require respondents to state on the record whether their questionnaire responses conform to prior rulings. Torrington claims that the Department also shifts the burden of proof upon petitioner by requiring petitioner to demonstrate, beyond a showing of below-cost transfer pricing, that foreign producers have in fact reimbursed dumping duties. Torrington also asserts that the Department places the burden of proof upon petitioner with regard to the reporting of product-specific R&D by allowing general allocations instead of product-specific allocations when respondents' annual reports mention new products. Torrington maintains further that the Department places the infeasible burden upon petitioner of proving, with regard to reseller transactions, that sales to HM buyers, related to U.S. OEMs or who distribute merchandise for export to third countries, are sales for export, not HM sales.

Torrington argues that, by shifting the burden of proof to petitioner, the Department has abdicated its fact-finding responsibilities and required the petitioner to perform the Department's investigation. Torrington cites *Rhone-Poulenc, Inc.* v. *Unites States,* 927 F. Supp. 451, 456–457 (CIT 1996), to support its contention. Torrington notes that the Department placed the burden of proof correctly upon respondents in these reviews with regard to duty absorption and that the burden should be similarly placed upon respondents for each issue parties address. Torrington concludes that, since respondents have had sufficient time to develop their records, the Department should not accept respondents' claims that they made their best efforts to substantiate their assertions.

NTN, SKF, and Koyo respond by stating that Torrington's argument is a vague, overly general criticism raised against all adjustments favorable to respondents. NTN argues that Department findings favorable to respondents do not shift the burden of proof to petitioner. Koyo argues that the Department is not required to investigate every claim petitioner alleges, and the Department required additional evidence correctly in support of petitioner's allegations of distortive adjustment methodologies. Koyo argues further that Torrington's position is similar to that taken by a party in *Al Tech Specialty Steel Corp.* v. *United States,* 575 F. Supp. 1277 (CIT 1983), in that the Department's requirement of additional information from petitioner when petitioner's claims were based on mere suspicion did not place an undue burden upon petitioner. Respondents argue that they and the Department have met their burdens of proof in that the Department has investigated petitioner's claims thoroughly and has conducted repeated verifications. SKF notes that it has provided thousands of pages of data in responding to the Department's questionnaires. NTN contends that the Department verified all of NTN's records regarding adjustments and reimbursement and found no evidence to support petitioner's claims. NTN notes, furthermore, that the cases petitioner cites to support its position, *Fujitsu General Ltd.,* v. *United States* and *Timken Co.* v. *United States,* are inappropriate because there is no basis for the Department to make a presumption of bad faith on the respondents' part, as was the situation in the cited cases. Koyo notes, moreover, that petitioner's argument regarding below-cost transfer pricing is immaterial since the level of transfer prices in relation to the benchmark Torrington proposes is irrelevant for determining whether the reimbursement of antidumping duties occurred. Finally, SKF argues that, contrary to petitioner's claims that the Department has abdicated its investigatory responsibilites, in the area of duty absorption—where petitioner approves of the Department's findings—the Department has invoked a methodology inappropriate in an investigatory fact-finding proceeding.

Department's Position: We agree with respondents that the petitioner does not bear an undue burden of proof in substantiating its claims. First, we disagree with petitioner's claim that our decision not to require respondents to state when they have disregarded prior determinations somehow results in or aggravates a shift in the burden of proof upon the petitioners. *See* our response to Comment 17(E). Second, we disagree that we shift the burden when we choose not to verify a particular respondent's data. As petitioner is aware, the Department has, over the course of the seven completed AFB reviews, verified all of the respondents subject to these 1995/96 reviews. The fact that respondents' data is subject to verification serves to ensure its accuracy. Moreover, where the Department has encountered difficulties in verifying a particular respondent's data, it has been careful to examine closely such information in later reviews.

With respect to the allocations at issue, the Department has examined fully and, in certain cases, verified respondents' data regarding petitioner's claims. Where we have been satisfied that a given allocation methodology is non-distortive, we have had no reason to require respondents to submit additional information. The mere fact that petitioner claims a methodology is distortive does not make it so. Where we have disagreed with petitioner, we have explained our positions throroughly in response to specific comments contained in this issues appendix. We have also addressed petitioner's allegations of reimbursement through below-cost transfer pricing (*see* our response to section 13, comment 1, above). In such cases, we have neither failed to meet our investigatory responsibilities nor placed an undue burden upon petitioner.

17.C. HTS.

Comment: Torrington argues that the Department should amend the list of HTS subheadings listed in the preliminary results by replacing HTS number 8482.99.6590, which Torrington claims does not currently exist, with HTS 8482.99.7060 and HTS 8482.99.7090 (1994 HTS) and also with HTS 8482.99.6560 and HTS 8482.99.6595 (1995 HTS and later). Torrington states that HTS 8482.99.6590 existed to cover parts of ball bearings and spherical plain bearings other than balls or races.

NSK agrees that HTS number 8482.99.6590 does not exist and should be removed from the references to the HTS classification in the final results. However, NSK states that Torrington did not describe accurately the HTS numbers and, along with SKF, suggests that the Department should examine the current HTS classifications applicable to scope merchandise before adding the references Torrington claims are appropriate.

Department's Position: We have confirmed that HTS number 8482.99.6590 has been deleted from the

1997 Harmonized Tariff Schedule and, therefore, we have removed it from the description of scope merchandise for the final results. We disagree with Torrington on the need to replace HTS 8482.99.6590 with HTS 8482.99.7060 and HTS 8482.99.7090 because these numbers refer to 1994 HTS numbers that no longer exist. Instead, after consulting with the U.S. Customs Service, we concluded that HTS 8482.99.6590 should be replaced with the 1997 HTS numbers HTS 8482.99.6560 and HTS 8482.99.6595. We also emphasize that HTS item numbers are provided for convenience and that the written descriptions of the scopes of the orders remain dispositive.

17.D. Certification of Conformance to Past Practice

Comment: Torrington claims that the Department should require all respondents to identify each instance where they have not followed previous Department rulings when responding to the Department's questionnaires. Torrington claims that, by accepting information which does not conform to previous agency determinations, the Department changes its position effectively without providing a reasoned explanation, which is contrary to administrative law. Torrington asserts that, when the Department does not verify questionnaire responses and respondents do not indicate where they have departed from prior agency rulings, then the quality of evidence upon which the Department relies is called into question profoundly under the substantial-evidence standard. Additionally, citing *Freeport Minerals Co.* v. *United States*, 776 F.2d. 1029 (CAFC 1985), among others, Torrington claims that the Department failed to discharge its affirmative duty to investigate and ascertain facts where (a) it knows that certain respondents take the position that they have no obligation to conform to prior agency rulings, and (b) it declines to take steps to ascertain whether those respondents are failing to conform.

Torrington analogizes the administration of the antidumping laws with customs-law enforcement. Torrington notes that, pursuant to 19 CFR 177.8(a)(2), importers are required to conform with prior customs rulings issued to the importer in question and suggests that the Department should take a parallel position in the administration of the antidumping law.

In addition, Torrington considers it illogical and unfair to continue an approach which requires the Department or Torrington to comb through every questionnaire response anew to detect instances wherein companies fail to follow prior rulings. Torrington states that respondents know when they are complying and where they are disregarding prior determinations. Torrington suggests that the Department should recognize this by requiring them to identify instances where their reporting reinstates a previously rejected method.

Torrington raises issues specifically pertaining to NTN and disagrees with NTN's position that it has no obligation to follow prior Department rulings expressly pertaining to NTN when answering subsequent Department questionnaires on the theory that each review is an independent proceeding, citing *AFBs V*, 61 FR at 66520–21. Torrington discusses several instances in which the Department rejected NTN's position in the various bearings reviews and suggests that the Department pursue the question carefully of whether NTN has disregarded prior negative rulings in these reviews. In Torrington's view, failure to apply past determinations when circumstances are essentially unchanged would constitute arbitrary administrative action and departures from precedent without explanation. If the Department cannot allay concerns on any of the foregoing pre-decided issues, Torrington urges the Department to resort liberally to facts available since Torrington believes that NTN should assume any risk of disregarding prior determinations.

NTN responds to Torrington's comments specifically addressing NTN's reporting methodology and states that, for four of Torrington's points, Torrington has mischaracterized NTN's reporting methodology. NTN observes that the CIT reversed the fifth issue. NTN claims that Torrington is unfamiliar with this case since it does not stand for the proposition that the Department may ''liberally resort to facts available'' when NTN has used a methodology with which Torrington disagrees. NTN also disagrees with Torrington's interpretation of the manner in which NTN has reported expenses and costs in prior segments of this proceeding.

Koyo submits that, if Torrington is to insist on such a practice, the Department should likewise restrict the issues that a petitioner may raise in its various filings in these proceedings to matters which have not already been addressed and rejected repeatedly by the Department and, often, by the Court of International Trade and not further appealed by the petitioner. Koyo suggests that, if Torrington persists with this proposal and the Department approves it, the Department should also restrict petitioners to matters not rejected previously.

SKF asserts that Torrington's reference to customs law is inapposite. SKF rebuts that one cannot compare a Customs tariff-classification ruling applicable to an entry of a particular type of merchandise to a complicated antidumping investigatory proceeding where, in any given review, hundreds or thousands of rulings and Department practices may be at issue. Moreover, SKF asserts that Customs has itself determined by rule that the cited entry procedure is necessary for the effective enforcement of the customs laws.

NTN, Koyo, SKF, NSK, and FAG disagree with Torrington's demand that respondents identify all cases where they are not following prior Departmental rulings and view the argument as pointless and impossible. Respondents state that Torrington has raised this argument in previous AFB reviews and the Department ultimately rejected Torrington's argument. Respondents point out that they are not bound by decisions in prior reviews as each administrative review is a distinct proceeding involving different sales, adjustments, and underlying facts and what transpired in previous reviews is not binding precedent in later reviews. Respondents also claim that Torrington has failed to provide any statutory support for such a drastic change in reported requirements. Respondents argue that Torrington's request be rejected because it would be unduly burdensome on both respondents and the Department.

Department's Position: We disagree with Torrington that we should require all respondents to conform their submissions, their allocations, and their methodology to our most recent determinations and rulings. In accordance with our usual practice, we also did not require respondents to identify where they have continued to use any methodology that we rejected in a prior review and justify the departure from established practice. Each administrative review is a separate reviewable proceeding involving different sales, adjustments, and underlying facts. What transpired in previous reviews is not binding precedent in later reviews and parties are entitled, at the risk of the Department's determining otherwise, to argue against a prior Department determination. As a practical matter, methodologies the Department accepts in one review are generally used by respondents in subsequent reviews and methodologies the Department rejects are not perpetuated in later reviews. The Department, however, may reconsider

its position on an issue during the course of the proceeding in light of facts and arguments presented by the parties. *See AFBs V* and *AFBs VI.*

While the issue of a party's conformance to the Department's previous rulings has been addressed in prior administrative reviews, Torrington raises a new argument in these reviews with respect to its analogy of the administration of the antidumping law with customs-law enforcement. We have considered this argument, but we did not find that we are required by statute to adopt Torrington's suggestions or that the administration of the antidumping statute would be best served by changing our practice in this regard.

17.E. Pre-Existing Inventory

Comment: SKF claims that SKF USA made some CEP sales of merchandise that entered into the United States prior to suspension of liquidation (November 9, 1988) and that, although SKF identified these sales in the questionnaire response, the Department did not exclude these sales from the margin calculations. SKF cites *Stainless Steel Wire Rod From France: Final Results of Antidumping Duty Administrative Review* (61 FR 27296, 27314 (Sept. 11, 1996))(*Wire Rods from France*) to support its argument that merchandise which entered the United States prior to the 1988 suspension of liquidation (and in the absence of affirmative critical-circumstances finding) is not subject merchandise and is therefore not subject to review by the Department. SKF asserts that it demonstrated at verification the accuracy of its tracing system, so the Department should be satisfied that these sales involve merchandise which entered the United States prior to the suspension of liquidation.

Torrington claims that, because sampling prevents the Department from linking a sale to an entry, it is incorrect to exclude any POR sales from the margin calculations. Torrington claims that SKF has neither demonstrated a link between these sales and entries made prior to the suspension of liquidation nor has it provided sufficient explanation of the circumstances involving the extended length of time these bearings spent in inventory.

Department's Position: The record regarding the alleged pre-November 9, 1988 entries is insufficient to satisfy us that SKF's country-of-origin tracking system establishes conclusively that the specific sales were of bearings which entered the United States prior to the original suspension of liquidation. SKF's only explanation, submitted in its case brief, is that its inventory system can link European invoices with receipts into inventory at the U.S. affiliate.

Therefore, SKF has not demonstrated a link between the entry to inventory and the sale to the unaffiliated party during the POR.

17.F. Inland Freight

Comment 1: Torrington contends that the Department should recalculate NTN Japan's reported HM pre-sale inland freight and U.S. inland freight expenses. Torrington maintains that determining these expenses based upon sales value yields distortive figures. Torrington points out that NTN Japan's current method of valuing these expenses date back to the LTFV investigation in which the Department permitted this approach because NTN Japan could not calculate a sale-by-sale freight expense. Torrington argues that these expenses should be valued based on weight and/or distance which are more relevant and accurate factors than sales value.

NTN Japan argues that it incurs the pre-sale freight and inland freight expenses regardless of weight. NTN Japan also contends that the Department has verified these expenses in previous reviews and has found that the basis upon which it calculates these expenses is not unreasonably distortive. NTN Japan therefore maintains that the Department should not recalculate freight on the basis of weight.

Department's Position: We agree with NTN Japan. We have accepted the methodology NTN Japan used in past reviews and did not find it to be distortive. *See AFBs VI* at 2122. Since there is nothing on the record in the current reviews that would indicate that a change in methodology is necessary, we have accepted NTN Japan's methodology for allocating freight expenses.

17.G. Other Issues

Comment: Agusta Aerospace Corporation (AAC), an importer of subject merchandise produced by SNFA France, argues that it is exempt from the antidumping duty order in this review pursuant to the Agreement on Trade in Civil Aircraft, 31 U.S.T. 619, April 12, 1979, (hereinafter ''the Agreement''). It maintains that the Agreement, which applies to aircraft, components and spare parts, provides that signatories agree to eliminate ''all customs duties and other charges of any kind levied on, or in connection with, the importation of products * * * if such products are for use in a civil aircraft and incorporation therein, in the course of its manufacture, repair, maintenance, rebuilding, modification or conversion * * *.'' (citing 31 U.S.T. 619, Art. 2). AAC asserts that the AFBs it imported during the POR were used as parts in A109 helicopters and such helicopters are exempt from duties under the Agreement. AAC argues further that the improved AFBs which it imported as a result of a mandate from its parent company should also be exempt from antidumping duties since the mandate from its parent company is functionally equivalent to AAC's parent company installing the bearings on the aircraft at manufacture. AAC concludes that, since the Agreement is an international treaty, the Department should not establish antidumping orders which conflict with it, absent express congressional language to the contrary.

AAC also argues that the Department should not assess antidumping duties on AAC's imported AFBs because AAC imports a relatively small amount of AFBs which comprise less than one percent of the total price of their completed aircraft. AAC argues further that, since AAC and its parent corporation permit only a finite, authorized market restricted to Agusta aircraft service centers and owners and operators of their aircraft to have access to the AFBs, the AFBs AAC imported cannot have a negative material impact on the U.S. AFB market since AAC has not authorized the U.S. AFB market to purchase AAC's AFBs. AAC concludes that, if the Department were to impose antidumping duties against AAC, the Department would defeat the purpose of the antidumping law, particularly since AAC cannot elect to purchase bearings by other manufacturers.

AAC challenges the Department's assessment of AFBs imported by AAC as adverse facts available and argues that the assessment is the unfair byproduct of SNFA's failure to respond to the Department's questionnaire. AAC argues that the Department should take into consideration the fact that, in its pre-preliminary results comments, AAC provided the Department with detailed import information but, given SNFA's refusal to respond, could not obtain information from SNFA. AAC argues that it lacks any authority or influence over SNFA to secure information from SNFA. AAC argues that the Department is punishing AAC for SNFA's unwillingness to cooperate in this review by rejecting the information AAC provided and by not requesting further information from AAC or its parent corporation.

Torrington rebuts that the Department should reject AAC's arguments. Citing *ASG Industries, Inc.* v. *United States,* 610 F. 2d 770, 777 n. 14 (1979),

Torrington states that antidumping and countervailing duties are imposed in addition to regular duties. Torrington also notes that, pursuant to Section 1335 of the Omnibus Trade and Competitiveness Act of 1988, the Department may exclude certain sales of bearings that have no substantial non-military use and are made pursuant to an existing Memorandum of Understanding, citing 61 FR 66471, 66508 (December 17, 1996). Torrington argues that AAC makes no such claim.

Department's Position: We disagree with AAC. The elimination of duties discussed in article 2 of the Agreement on Trade in Civil Aircraft refers to the elimination of ordinary customs duties, not antidumping duties imposed to offset unfair foreign trade practices. Indeed, U.S. law makes even U.S. government agencies acting as importers subject to antidumping or countervailing duties applicable to the merchandise imported unless it is merchandise ''acquired by, or for the use of,'' the Department of Defense from a country with which Defense had a Memorandum of Understanding in effect on January 1, 1988, or merchandise imported by Defense which ''has no substantial nonmilitary use.'' *See* section 771(20) of the Tariff Act; *AFBs V*, 61 FR 66,472, 66,508 (Dec. 17, 1996). *See also Federal-Mogul Corp.* v. *United States*, 813 F. Supp. 856, 865 n.6 (CIT 1993) (stating that in case of a conflict between GATT and U.S. law, U.S. law applies). Therefore, the Agreement on Trade in Civil Aircraft does not exempt AAC from the requirement to pay antidumping duties on the merchandise at issue.

We also reject AAC's request that it be exempted from the order because it imported and sold only a small amount of subject merchandise from SNFA during the POR and because it imported and installed the bearings in response to a ''mandate'' from its parent company. Neither the statute nor our regulations provides exemptions from the dumping law for such reasons. Thus, importing subject merchandise subject to a ''mandate'' is not ''functionally equivalent'' to installing merchandise on the aircraft at manufacture. Moreover, the fact that AAC's bearings comprise under one percent of the total price of the finished product when sold to unrelated customers does not exempt it from paying antidumping duties.

Finally, we have not used the information provided by AAC regarding its imports of SNFA bearings to calculate an antidumping duty rate for SNFA or AAC. In market-economy cases, the Department's practice is to calculate a single rate for each respondent investigated or reviewed. As AAC notes, however, SNFA did not respond to the Department's questionnaire. While we recognize the difficulty that AAC may have encountered in trying to obtain information from SNFA, the information provided by AAC was based on its own imports of subject merchandise and, absent SNFA's data, was insufficient to allow for the calculation of an antidumping duty rate. As stated in the SAA at page 826, imported components which are further manufactured are not exempt from antidumping duties.

[FR Doc. 97–27473 Filed 10–16–97; 8:45 am]
BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–351–820]

Ferrosilicon from Brazil: Amended Final Results of Antidumping Duty Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Amended final results of Antidumping Duty Administrative Review.

SUMMARY: On August 14, 1997, the Department of Commerce published the final results of the second administrative review of the antidumping duty order or ferrosilicon from Brazil. The review covered Companhia Ferroligas Minas Gerais-Minasligas and Companhia Brasileria Carbureto de Calcio manufacturers/exporters of the subject merchandise to the United States. The period of review is March 1, 1995 through February 29, 1996. Interested parties submitted ministerial error allegations with respect to the final results of administrative review for Minasligas on August 20, 1997. Based on the correction of certain ministerial errors made in the final results of review, we are amending our final results of review with respect to Minasligas and the All Others rate.

EFFECTIVE DATE: October 17, 1997.

FOR FURTHER INFORMATION CONTACT: Sal Tauhidi or Irene Darzenta, AD/CVD Enforcement Group II, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW, Washington, DC 20230, telephone: (202) 482–4851 or (202) 482–6320, respectively.

SUPPLEMENTARY INFORMATION:

Applicable Statute and Regulations

The Department of Commerce (the Department) has now amended the final results of this administrative review in accordance with section 751 of the Tariff Act of 1930, as amended (the Act). Unless otherwise indicated, all citations to the Act are references to the provisions effective January 1, 1995, the effective date of the amendments made to the Act by the Uruguay Round Agreements Act. In addition, unless otherwise indicated, all references to the Department's regulations are to the regulations set forth at 19 CFR part 353 (April 1996).

Background

On August 14, 1997, the Department published the final results of the second administrative review of the antidumping duty order or ferrosilcon from Brazil (62 FR 43504), covering the period March 1, 1995 through February 29, 1996. The respondents are Companhia Ferroligas Minas Gerais-Minasligas (Minasligas) and Companhia Brasileria Carbureto de Calcio (CBCC). The petitioners are Aimcor and SKW Metals & Alloys, Inc.

On August 20, 1997, the petitioners and Minasligas filed allegations that the Department had made certain ministerial errors in this administrative review with respect to Minasligas. Specifically, the petitioners alleged three ministerial errors with respect to the following issues: (1) the use of Brazilian reais-denominated gross unit prices instead of U.S. dollar-denominated gross unit prices for U.S. sales; (2) the treatment of marine insurance expenses for certain U.S. sales; and (3) the date of sale for one U.S. sale. Minasligas alleged two ministerial errors with respect to the following issues: (1) the adjustment to U.S. price for insurance revenue applicable to one U.S. sale; and (2) the treatment of value-added taxes (VAT) on U.S. sales. On August 27, 1997, both parties submitted comments on these allegations. For a complete discussion of the allegations, *see* the Department's October 6, 1997, Decision Memorandum Re: Alleged Ministerial Errors in the Calculation of the Final Antidumping Duty Margin for Companhia Ferroligas Minas-Gerais-Minasligas.

As discussed below, in accordance with 19 CFR 353.28(d), we have determined that certain ministerial errors were made in our margin calculations for Minasligas. In addition, the Department also determined that a clerical error was made regarding the

''All Others'' rate as stated in the notice of the final results.

Scope of Review

The merchandise subject to this review is ferrosilicon, a ferro alloy generally containing, by weight, not less than four percent iron, more than eight percent but not more than 96 percent silicon, not more than 10 percent chromium, not more than 30 percent manganese, not more than three percent phosphorous, less than 2.75 percent magnesium, and not more than 10 percent calcium or any other element. Ferrosilicon is a ferro alloy produced by combining silicon and iron through smelting in a submerged-arc furnace. Ferrosilicon is used primarily as an alloying agent in the production of steel and cast iron. It is also used in the steel industry as a deoxidizer and a reducing agent, and by cast iron producers as an inoculant. Ferrosilicon is differentiated by size and by grade. The sizes express the maximum and minimum dimensions of the lumps of ferrosilicon found in a given shipment. Ferrosilicon grades are defined by the percentages by weight of contained silicon and other minor elements. Ferrosilicon is most commonly sold to the iron and steel industries in standard grades of 75 percent and 50 percent ferrosilicon. Calcium silicon, ferrocalcium silicon, and magnesium ferrosilcon are specifically excluded from the scope of this review. Calcium silicon is an alloy containing, by weight, not more than five percent iron, 60 to 65 percent silicon, and 28 to 32 percent calcium. Ferrocalcium silicon is a ferro alloy containing, by weight, not less than four percent iron, 60 to 65 percent silicon, and more than 10 percent calcium. Magnesium ferrosilicon is a ferro alloy containing, by weight, not less than four percent iron, not more than 55 percent silicon, and not less than 2.75 percent magnesium.

Ferrosilicon is currently classifiable under the following subheadings of the Harmonized Tariff Schedule of the United States (HTSUS): 7202.21.1000, 7202.21.5000, 7202.21.7500, 7202.21.9000, 7202.29.0010, and 7202.29.0050. Although the HTSUS subheadings are provided for convenience and customs purposes, our written description of the scope of this review is dispositive. Ferrosilicon in the form of slag is included within the scope of this order if it meets, in general, the chemical content definition stated above and is capable of being used as ferrosilicon. Parties that believe their importations of ferrosilicon slag do not meet these definitions should contact the Department and request a scope determination.

Alleged Ministerial Errors

Issue 1: The Use of Brazilian Reais-denominated Gross Unit Prices Instead of U.S. Dollar-denominated Gross Unit Prices for U.S. Sales

The petitioners contend that because the Department believed that Minasligas' U.S. dollar prices were not on the record, it used Brazilian reais-denominated gross unit prices instead of U.S. dollar-denominated gross unit prices for U.S. sales in its margin analysis. The Department thus mistakenly converted the U.S. sales prices reported in Brazilian currency to U.S. dollars on the date of sale. However, the petitioners assert that in Exhibit 6 of Minasligas' October 11, 1996 supplemental response, Minasligas reported the gross unit prices for its U.S. sales in U.S. dollars. The petitioners argue that the Department should have used the U.S. dollar-denominated gross unit prices for Minasligas' U.S. sales, as reported in Exhibit 6 of Minasligas' October 11, 1996 supplemental response, instead of the Brazilian reais-denominated gross unit prices in its margin analysis.

Minasligas contends that because the Department was able to verify the accuracy of the Brazilian reais-denominated prices by examining relevant commercial invoices for selected U.S. sales at verification, it should reject petitioners' request to use the U.S. dollar-denominated gross unit prices reported in Exhibit 6. In this respect, Minasligas argues that the Department did not make a clerical error but applied an appropriate methodology.

DOC Position

We agree with the petitioners. In the final results of review, the Department mistakenly concluded that Minasligas' U.S. dollar-denominated gross unit prices for U.S. sales were not on the record and, therefore, used the Brazilian reais-denominated U.S. prices in its final margin analysis. Upon further review of the record, we find that Minasligas reported U.S. dollar-denominated prices in Exhibit 6 of its October 11, 1996 supplemental response and that these prices were consistent with sales documentation obtained at verification. Thus, we inadvertently omitted the U.S. dollar-denominated price data contained in Exhibit 6 from our original final margin analysis. For complete discussion and analysis *see* the Department's October 6, 1997, Decision Memorandum Re: Alleged Ministerial Errors in the Calculation of the Final Antidumping Duty Margin for Companhia Ferroligas Minas-Gerais-Minasligas. Therefore, for these amended final results, we have used the U.S. dollar-denominated gross unit prices for U.S. sales as reported in Exhibit 6 of Minasligas' October 11, 1996 supplemental response.

Issue 2: Clerical Error Allegations Regarding the Treatment of Marine Insurance Expenses for Certain U.S. Sales, the Date of Sale for One U.S. Sale, and the Adjustment to U.S. Price for Insurance Revenue Applicable to One U.S. Sale

The petitioners and Minasligas contend that the Department failed to correctly input certain data for certain U.S. sales in its final margin calculations. Specifically, the petitioners contend that the Department made input errors with respect to marine insurance expenses for certain U.S. sales and the date of sale for one U.S. sale. Minasligas contends that the Department made an input error with respect to the adjustment to U.S. price for insurance revenue applicable to one U.S. sale.

DOC Position

We agree with both the petitioners and Minasligas' allegations and have corrected these clerical errors. For complete discussion and analysis, *see* the Department's October 6, 1997, Decision Memorandum Re: Alleged Ministerial Errors in the Calculation of the Final Antidumping Duty Margin for Companhia Ferroligas Minas-Gerais-Minasligas.

Issue 3: Value-added Taxes Collected on U.S. Sales

Minasligas asserts that the Department stated in its final results that Minasligas was unable to substantiate its claim that VAT charges are passed along to U.S. customers and are included in the reported U.S. prices. Minasligas maintains that for purposes of making price-to-price comparisons, however, the Department treated VAT on U.S. export sales as if it had been passed along to U.S. customers and included it in the U.S. price. According to Minasligas, there is a contradiction between the Department's finding of fact (*i.e.*, that Minasligas was unable to substantiate its claim that VAT charges are passed along to U.S. customers and are included in the reported prices) and the Department's calculation methodology. Minasligas maintains that if the Department's finding of fact is correct, it was a mistake to deduct VAT from the U.S. price or to account for it

in price-to-price comparisons. However, if the Department's finding of fact is not correct, Minasligas maintains that it is the Department's practice to calculate U.S. imputed credit expenses based on a U.S. price exclusive of VAT.

The petitioners contend that the Department did not subtract VAT taxes on U.S. sales from the U.S. price. Instead, petitioners argue that the Department determined the difference between the weighted-average per unit VAT taxes collected on home market sales and the per-unit VAT taxes owed by Minasligas on each U.S. sale, and then subtracted this difference from normal value (NV) which included VAT taxes collected on home market sales, in accordance with its normal practice.

Department's Position

We agree with Minasligas that this adjustment was inappropriate. For complete discussion and analysis, *see* the Department's October 6, 1997, Decision Memorandum Re: Alleged Ministerial Errors in the Calculation of the Final Antidumping Duty Margin for Companhia Ferroligas Minas-Gerais-Minasligas. Therefore, for these amended final results, we have not made an adjustment to NV for VAT on U.S. sales.

Issue 4: All Others Rate

The Department erroneously reported an ''All Others Rate'' of 91.06 percent in the notice of final results. The correct ''All Others Rate'' is 35.95 percent. (*See Amended Final Determination of Sales at Less Than Fair Value (LTFV): Ferrosilicon from Brazil*, 59 FR 8599, February 23, 1995.) Thus, we are amending the final results to replace the incorrect rate of 91.06 percent with the correct rate of 35.95 percent.

Amended Final Results

As a result of our correction of the ministerial errors for Minasligas, we have determined the following amended margin exists for Minasligas for the period covering March 1, 1995 through February 29, 1996:

Manufacturer/Exporter	Amended Weighted-Average Margin (percent)
Minasligas	2.54

The Department shall determine, and the U.S. Customs Service shall assess, antidumping duties on all appropriate entries. The Department will issue appraisement instructions concerning the respondent directly to the U.S. Customs Service.

Furthermore, the following cash deposit requirements will be effective for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date of these amended final results of administrative review, as provided for by section 751(a)(1) of the Act: (1) the cash deposit rate for the reviewed company named above will be the rate as stated above; (2) for previously investigated or reviewed companies not listed above, the cash deposit rate will continue to be the company-specific rate published for the most recent period; (3) if the exporter is not a firm covered in this review, or the original LTFV investigation, but the manufacturer is, the cash deposit rate will be the rate established for the most recent period for the manufacturer of the merchandise; and (4) if neither the exporter nor the manufacturer is a firm covered in this review, the cash deposit rate for all other manufacturers or exporters will be 35.95 percent, the All Others rate established in the amended final LTFV investigation. These deposit requirements, when imposed, shall remain in effect until publication of the final results of the next administrative review.

This notice services as the final reminder to importers of their responsibility under 19 CFR 353.26 to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

This notice also serves as a reminder to parties subject to administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 353.34(d). Timely written notification of return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with regulations and the terms of the APO is an sanctionable violation.

These amended final results of administrative review and notice are in accordance with section 751(a)(1) of the Tariff Act (19 U.S.C. 1675(a)(1) and 19 CFR 353.28(c)).

Dated: October 10, 1997.

Robert S. LaRussa,

Assistant Secretary for Import Administration.

[FR Doc. 97–27631 Filed 10–14–97; 3:02 pm]

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DEPARTMENT OF COMMERCE

International Trade Administration

[A–351–806]

Silicon Metal From Brazil; Amended Final Results of Antidumping Duty Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Amended final results of antidumping duty administrative review.

SUMMARY: The Department of Commerce (the Department) is amending its final results of review, published on January 14, 1997, of the antidumping duty order on silicon metal from Brazil, to reflect the correction of ministerial errors in those final results. The period covered by these amended final results is the period July 1, 1994 through June 30, 1995.

EFFECTIVE DATE: October 17, 1997.

FOR FURTHER INFORMATION CONTACT: Fred Baker, Alain Letort, or John Kugelman, AD/CVD Enforcement Group III—Office 8, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, N.W., Washington, D.C. 20230, telephone 202/482–2924 (Baker), 202/482–4243 (Letort), or 202/482–0649 (Kugelman), fax 202/482–1388.

SUPPLEMENTARY INFORMATION:

Applicable Statute and Regulations

Unless otherwise indicated, all citations to the Act are references to the provisions effective January 1, 1995, the effective date of the amendments made to the Act by the Uruguay Round Agreements Act (URAA).

Background

The Department published the final results of the fourth administrative review, covering the period July 1, 1994 through June 30, 1995, of the antidumping duty order on silicon metal from Brazil on January 14, 1997 (62 FR 1970) (*Fourth Review Final Results*). The respondents are Companhia Brasileira Carbureto de Cálcio (CBCC), Companhia Ferroligas Minas Gerais-Minasligas (Minasligas),

Eletrosilex Belo Horizonte (Eletrosilex), Rima Industrial S.A. (RIMA), and Camargo Corrêa Metais (CCM). The petitioners are American Alloys, Inc., Elken Metals, Co., Globe Metallurgical, Inc., SMI Group, and SKW Metals & Alloys.

On January 31, 1997, Minasligas and RIMA filed clerical error allegations. On February 4, 1997, the petitioners filed clerical error allegations with respect to Eletrosilex, Minasligas, RIMA, and CBCC. On February 6, 1997, Eletrosilex filed clerical error allegations. On February 7, 1997, petitioners filed a response to the clerical error allegations submitted by Minasligas and RIMA. Also on February 7, 1997, RIMA submitted a response to the petitioners' clerical error allegations. On February 11, 1997, CBCC submitted a response to petitioners' clerical error allegations. On February 13, 1997, petitioners submitted a response to Eletrosilex's clerical error allegations. Pursuant to the CIT's order, we are now addressing the ministerial allegations and amending our final results of the fourth review. *See American Silicon Technologies et al., v. United States,* Slip Op. 97–113, August 18, 1997.

Scope of Review

The merchandise covered by this review is silicon metal from Brazil containing at least 96.00 percent but less than 99.99 percent silicon by weight. Also covered by this review is silicon metal from Brazil containing between 89.00 and 96.00 percent silicon by weight but which contains a higher aluminum content than the silicon metal containing at least 96.00 percent but less than 99.99 percent silicon by weight. Silicon metal is currently provided for under subheadings 2804.69.10 and 2804.50 of the Harmonized Tariff Schedule (HTS) as a chemical product, but is commonly referred to as a metal. Semiconductor grade silicon (silicon metal containing by weight not less than 99.99 percent silicon and provided for in subheading 2804.61.00 of the HTS) is not subject to the order. HTS item numbers are provided for convenience and for U.S. Customs purposes. The written description remains dispositive as to the scope of product coverage.

Clerical Error Allegations

Comment 1

Minasligas argues that the Department erred in its calculation of its cost of production/constructed value (COP/CV) by failing to offset Minasligas' financial expenses with its financial income. That Minasligas had short-term financial income, Minasligas argues, is evident from its 1994 financial statement. Minasligas argues that there are three categories of financial income which the Department erroneously determined not to allow as an interest income offset. The first is ''income from short term applications,'' which Minasligas alleges the Department disallowed as an offset because it mistook it to be compensation for inflation. In fact, Minasligas argues, the record shows that the effects of inflation are reflected on the financial statements through the recording of monetary correction of fixed assets, shareholders equity, and other accounts subject to such correction. Thus, Minasligas argues, the Department cannot interpret Minasligas' submissions or its financial statements to indicate that inflation is included in ''income from short term applications.''

The second category of income which the Department erroneously failed to include as an offset to Minasligas' financial expenses, Minasligas argues, is the category ''exchange gains.'' Minasligas argues that the Department should include exchange gains as an offset to financial expenses because it included exchange losses as a financial expense.

The third category of income which the Department erroneously failed to include as an offset to financial expenses, Minasligas argues, is the category ''gains on monetary correction.'' Minasligas argues that the Department should include this category of income as an offset to financial expenses because it included an amount for monetary correction of loans (*i.e.*, the inflation adjustment on monetary liabilities) in financial expenses.

Petitioners argue that the Department's calculation of Minasligas' financial expenses was correct. It cites the final results notice in which the Department stated:

> [A]lmost all of Minasligas' reported ''interest income'' consists of items that are totally unrelated to interest income. The financial statements for Minasligas and its parent, Delp Engenharia Mecanica S.A. (Delp), demonstrate that over 95 percent of both companies' reported ''interest income'' consists of ''monetary variation,'' ''monetary correction,'' and ''income from short-term applications.'' The Department's verification report for Minasligas in the immediately preceding review clarifies that ''financial applications'' (which would include ''income from short-term applications'') refers to compensation for inflation. At no point has Minasligas demonstrated for the record that the amounts reported for these categories of income constitute interest income derived from short-term investments of working capital. Nor has Minasligas demonstrated that the claimed interest income was derived from short-term investments of working capital merely by stating in its rebuttal brief that its net interest income exceeded its net interest expense.
>
> Similarly, the financial statements submitted by Minasligas show that the category ''interest received'' included *inter alia*, (1) charges paid by customers for Delp's granting of delayed payment terms, which are really sales revenue; (2) discounts obtained from suppliers; (3) dividends received; and (4) exchange gains or losses. See Minasligas' April 30, 1996 SQR at 37 and exhibit 19. These items clearly do not represent interest income from short-term investments.
>
> For the above reasons, we have reduced Minasligas' interest income by the total amount of the items incorrectly included therein by Minasligas (see Final Analysis Memorandum from Fred Baker to the File).

See Fourth Review Final Results, at 1974. Based on the analysis in the final results, petitioners argue that the Department's calculation of Minasligas' interest expense was neither a ministerial nor a non-ministerial error.

Department's Position: As petitioners have noted, we addressed this issue in the final results of the fourth review. Our treatment of Minasligas' financial income was intentional, and not a ministerial error. The disagreement Minasligas has expressed is in regard to our analysis, and is thus not a proper subject for review under the ministerial errors correction process.

Comment 2

Minasligas argues that the Department made a ministerial error in its revaluation of Minasligas' beginning inventory. The Department, based on Minasligas' October 15, 1996 submission, revalued Minasligas' beginning inventory in order to account for hyperinflation that occurred prior to the start of the period of review (POR). The raw material costs Minasligas reported in its October 15, 1996 submission, it argues, were its inventory of both ferrosilicon and silicon metal. Minasligas states that the Department did not request that Minasligas report silicon metal inventory separately, nor could Minasligas have done so because it does not maintain separate inventory records. Minasligas argues that the Department mistakenly overstated the adjustment to the reported silicon metal costs by calculating an inflation adjustment on raw materials for the entire company, and applying the additional costs entirely to silicon metal, rather than proportionately to subject and non-subject merchandise.

Petitioners argue that there is no evidence on the record, and Minasligas has cited to none, to support Minasligas' claim. For this reason, petitioners argue,

the Department should reject Minasligas' argument. Furthermore, petitioners point out that in its April 30, 1996 supplemental questionnaire response, Minasligas stated that it maintains separate inventories for charcoal. Thus, petitioners argue, Minasligas' argument that it does not maintain separate inventory records for its raw materials is contradicted by other information on the record, at least with respect to charcoal.

Department's Position: We agree with both parties in part. We agree with Minasligas that the revalued costs should be allocated to silicon metal so that ferrosilicon costs are not attributed to silicon metal, and that it would be an error not to perform an allocation where one is warranted. However, we agree with petitioners that Minasligas has cited to no evidence on the record that the inventory volumes and values Minasligas reported in its October 15, 1996 submission were its entire inventory of raw materials used in the production of both ferrosilicon and silicon metal. Our review of the record indicates that the figures for charcoal Minasligas' reported in its October 15, 1996 submission reflects its entire inventory for charcoal, but the figures it reported in its October 15, 1996 submission for woodchips, quartz, and carbon electrodes reflects only the inventory used in the production of silicon metal. We made this determination based on the value of material inputs Minasligas reported in tab 8 of its April 30, 1996 submission (where Minasligas reported the value of its inputs for silicon metal), as compared to the material input values Minasligas reported in its October 15, 1996 submission, which Minasligas now alleges reflects its entire inventory of the four inputs. These two exhibits demonstrate that the cost figures Minasligas reported for woodchips, quartz, and carbon electrodes in the production of silicon metal in tab 8 of its April 30, 1996 submission are identical to those it reported in its October 15, 1996 submission. However, such is not the case for charcoal. Furthermore, other evidence on the record indicates that the consumption volume figures Minasligas reported for charcoal were used in the production of silicon metal and ferrosilicon (*see* tab 18 (exhibit 36c) of its April 30, 1996 submission). Therefore in these amended final results, we have performed an allocation of the revalued costs only for charcoal. We performed the allocation based on the volume of charcoal consumed in the production of silicon metal relative to the volume of charcoal consumed in the production of ferrosilicon. *See* the amended final results analysis memorandum for our calculations.

Comment 3

Minasligas argues that the Department made a ministerial error by double-counting packing costs in COP/CV. It argues that the Department added packing costs to a COP which already included packing costs. It argues that the Department failed to deduct home-market packing costs from the cost of manufacture (COM) before adding U.S. packing costs in calculating CV.

Petitioners argue that information on the record indicates that the Department double-counted only the labor and machine costs for packing, and not the cost of packing materials. *Department's Position:* We agree with petitioners that we double-counted only the labor and machine costs for packing, and not the material costs. In these amended final results of review we have revised our calculations of COP and CV so as not to double-count labor and machine costs. *See* the amended final results analysis memorandum for our calculations.

Comment 4

Minasligas argues the Department made three errors in calculating profit for CV. The first alleged error was that the Department based profit on Minasligas' financial statement data, rather than on the actual profit calculated on above-cost sales of subject merchandise. Minasligas argues that this was an error because the statute directs the Department to add to CV the ''actual amounts incurred and realized by the specific exporter or producer being examined in the investigation or review for selling, general, and administrative expenses, and for profits, in connection with the production and sale of a foreign like product, in the ordinary course of trade for consumption in the foreign country* * *'' 19 U.S. 1677b(e)(2)(A). Based on this statutory language, Minasligas argues that the Department is required to calculate profit based on above-cost sales wherever possible.

Furthermore, Minasligas argues that in calculating profit based on above-cost sales, the Department erred by limiting the calculation to only the sales of regular grade silicon metal. Rather, Minasligas argues, the Department should have included sales of both regular and high-purity grade silicon metal even if all the U.S. sales to be compared to CV are regular-grade silicon metal. Minasligas contends that the Department has in the past based profits on the entire foreign like product, and not on a subset of the subject merchandise. In support of this contention, it cites *Antifriction Bearings (Other than Tapered Roller Bearings) and Parts Thereof from France, Germany, Italy, Japan, Singapore, and the United Kingdom; Final Results of Antidumping Duty Administrative Reviews,* 62 F.R. 2081, 2112–2114 (January 15, 1997), where the Department rejected a respondent's argument that where there are no appropriate identical or family matches (and hence the Department uses CV), there are no sales of ''a foreign like product'' to calculate a profit margin. In further support of this contention, Minasligas cites *Professional Electric Cutting Tools from Japan; Final Results of Antidumping Duty Administrative Review,* 62 F.R. 386, 389–390 (January 3, 1997), in which the Department stated, ''For purposes of calculating CV and CEP profit, we interpret the term 'foreign like product' to be inclusive of all merchandise sold in the home market which is in the same general class or kind of merchandise as that under consideration,'' and *Notice of Final Determination of Sales at Less than Fair Value: Large Newspaper Printing Presses and Components Thereof, Whether Assembled or Unassembled, from Japan,* 61 F.R. 38139, 38145–38147 (July 23, 1996), in which the Department stated, ''[Respondent] is incorrect to suppose that because we did not find home-market sales which provided practicable price-to-price matches, no foreign like product existed. The foreign like product . . . did exist, as revealed by our examination of . . . equipment sold in the home market for purposes of the Department's home-market viability test.''

The second alleged error the Department made was using an allegedly incorrect total profit figure to calculate Minasligas' profit ratio. In calculating the total profit figure, the Department included the line item for interest income found on Minasligas' 1994 financial statement. Minasligas argues that it was an error for the Department to reject the line item for interest income as an offset to financial expenses (presumably because it was unrelated to production of the foreign like product) but to include it in the calculation of profit. It argues that if the interest income is unrelated to production then it cannot be used for the purpose of calculating CV.

The third alleged error that the Department made was its failure to apply the profit cap required by the statute. Minasligas argues that the

statute allows profit to be calculated in one of three ways:

(i) the actual amounts incurred and realized by the specific producer for profits, in connection with the production and sale for consumption in the foreign country, of merchandise that is in the same general category of products as the subject merchandise;

(ii) the weighted average of the actual amounts incurred and realized by producers that are subject to the review for profits in connection with the production and sale of a foreign like product, in the ordinary course of trade, for consumption in the foreign country; or

(iii) the amounts incurred for profits based on any other reasonable method, except that the amount allowed for profit may not exceed the amount normally realized by exporters or producers in connection with the sale, for consumption in the foreign country, of merchandise that is in the same general category of products as the subject merchandise.

See 19 U.S.C. 1677b(e)(2)(B). Minasligas argues that the Department's method of calculating profit does not comport with either items (i) or (ii), and therefore must have been (iii). Thus, Minasligas argues, the statutory profit cap applies, but the amount the Department calculated for profit exceeded this cap because it exceeded the amount normally realized by other exporters or producers.

Petitioners retort that the Department did not make an error in the calculation of Minasligas' profit. First, they contend that the statute requires not that sales of subject merchandise be used in the calculation of profit (as Minasligas claims), but that actual amounts for profits ''in connection with the production and sale of a foreign like product'' be used. *See* 19 U.S.C. 1677(16). Second, petitioners argue that the Department's regulations define the term ''ministerial error'' as ''an error in addition, subtraction, or other arithmetic function, clerical error resulting from inaccurate copying, duplication or the like, and any other type of unintentional error which the Secretary considers ministerial.'' Based on this definition, petitioners argue that the Department's calculation of profit was not a ministerial error. Indeed, petitioners argue, the Department's analysis memorandum demonstrates that it acted intentionally when it calculated profit as it did. Third, petitioners argue that the Department does not have on the record of the review the information necessary to calculate a profit cap in accordance with the statute. Thus, petitioners argue, the Department properly calculated Minasligas' profit on a facts-available basis because the Statement of Administrative Action states that the Department may do so under such circumstances.

Department's Position: We agree with petitioners that our calculation of profit did not constitute a clerical error. Our calculation of profit used in the programming is identical to that described in the final results analysis memorandum for Minasligas. *See* the January 24, 1997 analysis memorandum, pp. 4 and 5.

Comment 5

Minasligas argues that the Department erred in its calculation of CV by calculating general and administrative expenses (G&A), profit, and financial expense ratios as a percentage of cost of goods sold (which does not include value-added taxes) and applying these ratios to a COM which includes value-added taxes. It argues that since the value-added taxes are not reflected anywhere as a cost on Minasligas' audited financial statements, it would be inappropriate to calculate a G&A, profit, or financial expense ratio from its financial statements and then apply the ratio to a COM which includes value-added taxes. Similarly, RIMA and Eletrosilex argue that the Department erred in its calculation of CV by calculating G&A and financial expense ratios as a percentage of cost of goods sold (COGS) from their 1994 financial statements (which do not include value-added taxes and depreciation expenses) and applying them to a COM which does include value-added taxes and depreciation expenses. RIMA also argues that the Department erred in its calculation of financial expenses by calculating a ratio which includes late payment fees, and applying it to a COM which also includes late payment fees. By so doing, RIMA argues, the Department double-counted late payment fees.

Furthermore, Minasligas argues that the Department's calculation of CV was inconsistent with the statute because the G&A and interest expense values used in CV are different from those used in COP. Minasligas argues that because 19 U.S.C. § 1677b(e)(2)(A) requires the Department to base selling, general, and administrative expenses on the actual amounts incurred and realized in production of the foreign like product, and because the actual amount of G&A and interest does not differ for the product between CV and COP, the Department's method was a violation of the statute.

Petitioners argue, with respect to Eletrosilex, that the Department made no error in its calculations. It argues that the Department did not, contrary to Eletrosilex's claims, calculate its G&A ratio from Eletrosilex's financial statements. Instead, petitioners state, the Department used the monthly G&A expenses that Eletrosilex reported in exhibit 36 of its October 20, 1995 questionnaire response. With respect to Eletrosilex's financial expenses, petitioners argue that the COM does not include the depreciation that the Department calculated, nor does it include the ICMS tax (a value-added tax).

Department's Position: We agree with respondents that where the COGS recorded on the financial statements do not include value-added taxes or depreciation, the COM values used to calculate profit, G&A, and interest for CV should be net of value-added taxes or depreciation in order to avoid overstating these expenses. Therefore, in these amended final results of review, we have calculated CV using G&A, profit, and interest expense figures for Minasligas and RIMA based on a COM that is net of value-added taxes and (for RIMA) net of depreciation. We also agree with RIMA that because late payment fees were included in the financial expenses reported on its financial statement, we would double count late payment fees by including them in the COM used to calculate interest expenses. Therefore, in these amended final results, we have removed the late payment fees from the financial expenses in calculating RIMA's financial expense ratio.

With respect to Eletrosilex, we agree with petitioners that, in the final results, we did not include all value-added taxes in the COM used to calculate Eletrosilex's interest expenses for CV. (We included only the IPI, and not the ICMS.) Therefore, in these amended final results of review, we have removed the IPI from the COM used to calculate interest. Furthermore, we also agree with petitioners that we did not calculate Eletrosilex's G&A from its financial statement, but instead used the monthly G&A figures it submitted in exhibit 36 of its October 20, 1995 questionnaire response. However, we disagree with petitioners that the COM we used to calculate Eletrosilex's interest was net of depreciation. Therefore in these amended final results, we have calculated Eletrosilex's interest using a COM that is net of depreciation.

Comment 6

Minasligas and RIMA argue that the Department made a clerical error in the calculation of CV by increasing normal value (NV) by the amount of U.S. imputed credit expenses, but not reducing NV by the amount of imputed home-market credit expenses. They argue that the Department should subtract imputed home-market credit from NV.

Petitioners argue that the Department was correct in not subtracting home-market credit from NV. They argue that the Department's practice is to include only actual, not imputed, expenses in CV. Therefore, petitioners say, because the Department did not include home-market imputed credit expenses in CV, it would have been wrong to subtract home-market imputed credit expenses from CV when making the circumstance-of-sale adjustment for imputed credit.

Department's Position: We agree with respondents that our failure to subtract imputed credit from the calculation of CV constituted a ministerial error. It is our practice to make a circumstance-of-sale adjustment for differences in credit costs between the home and U.S. markets even in a CV margin calculation. Hence, we have done so in these amended final results.

Comment 7

Minasligas argues that the Department erred in its computation of net home-market price and home-market credit by including in the computation the addition of a variable representing the PIS/COFINS taxes. The Department included this variable in the preliminary results of review, but its final results analysis memorandum indicates that the Department intended to delete it for the final results. Minasligas argues that the Department did not do so.

Department's Position: We agree, and have corrected this error in these amended final results.

Comment 8

Minasligas, RIMA, and Eletrosilex argue that the Department erred by failing to deduct from CV the difference between the ICMS tax due on home-market sales and on U.S. sales. To support their argument, Minasligas, RIMA, and Eletrosilex cite the Department as stating in the final results: ''In order to achieve tax neutrality with respect to the ICMS tax we should deduct from NV only the amount of the difference between ICMS tax due on home-market sales and ICMS tax due on U.S. sales.'' *See Fourth Review Final Results* at 1983. Furthermore, Minasligas, RIMA, and Eletrosilex argue that the Department has in the past stated that its practice is to make circumstance-of-sale adjustments in price-to-CV as well as price-to-price margin calculations. *See Tapered Roller Bearings and Parts Thereof Finished or Unfinished from Japan*, 52 FR 30700 (August 17, 1987).

Petitioners argue that the language cited by Minasligas, RIMA, and Eletrosilex applies only to price-to-price comparisons, and not price-to-CV comparisons. Petitioners argue that the correct interpretation of the Department's statement cited by Minasligas is governed by another statement the Department made in the same context: ''This approach is in accordance with 19 U.S.C. § 1677b(a)(6)(B)(iii).'' This section of the statute, petitioners argue, refers to price, and not CV. It states that ''the price described in paragraph (1)(B) shall be * * *reduced by* * * * the amount of any taxes imposed directly upon the foreign like product or components thereof which have been rebated, or which have not been collected, on the subject merchandise, but only to the extent that such taxes are added to or included in the price of the foreign-like product.''

Department's Position: We disagree with respondents that our treatment of ICMS taxes in a CV situation constitutes a ministerial error. We intended to treat ICMS taxes in a CV situation exactly as we did in the final results. Therefore, this issue is a methodological issue, and not a proper subject for review under the ministerial errors correction process.

Comment 9

Minasligas, RIMA, and Eletrosilex argue that the Department made a clerical error in calculating U.S. imputed credit by dividing the annual interest rate by 30 rather than 365.

Department's Position: We agree, and have corrected this error in these amended final results.

Comment 10

RIMA argues that the Department incorrectly calculated depreciation. In the final results, the Department stated that it based its calculation of RIMA's depreciation on facts available, and explained:

> As facts available the Department has chosen to use one-half of the audited total RIMA depreciation expenses for the fiscal year as RIMA's total POR depreciation expenses, and to allocate to silicon metal production a share of that total based on the highest monthly percentage of cost of goods sold accounted for by silicon metal, as appearing in verification exhibit OH1. We allocated one-twelfth of this total, in turn, to each month of the POR.

See Fourth Review Final Results, at 1984. RIMA argues that the Department failed to divide the total depreciation by two as is necessary if the calculated amount is to be ''*one-half* of the audited total RIMA depreciation expenses for the fiscal year,'' as described above.

Petitioners argue that the Department's calculations, as laid out in the January 24, 1997 final results analysis memorandum, indicate that the Department did in fact divide total depreciation by two.

Department's Position: We agree with petitioners. The attachment labeled ''Calculation of RIMA's Depreciation—4th Review'' in the final results analysis memorandum for RIMA indicates that the Department did divide the depreciation expenses in half. Thus, we did not make a clerical error.

Comment 11

Petitioners argue that the Department made a clerical error in its calculations for Eletrosilex by failing to add U.S. imputed credit expenses to CV.

Department's Position: We agree, and have corrected this error in these amended final results.

Comment 12

Petitioners argue the Department made a clerical error in its calculations for Eletrosilex by adding U.S. post-sale warehousing expenses expressed in Brazilian currency to a CV expressed in U.S. dollars.

Department's Position: We agree, and have corrected this error in these amended final results.

Comment 13

Petitioners argue that the Department made a clerical error in its calculations for CBCC by adding, rather than subtracting, international freight from United States Price (USP).

Department's Position: We agree, and have corrected this error in these amended final results.

Comment 14

Petitioners argue that the Department made a clerical error in its calculations for CBCC by treating the bank charges incurred to finance some of CBCC's U.S. sales as expressed in U.S. dollars, rather than in Brazilian currency.

Department's Position: We agree, and have corrected this error in these amended final results.

Comment 15

Petitioners argue that the Department made a clerical error in its calculations

of USP for some of CBCC's U.S. sales by including in the computer field ''BANKCHRG'' only the cost of interest, and not the cost of bank charges.

Department's Position: We agree, and have corrected this error in these amended final results.

Comment 16

Petitioners argue that the Department made a clerical error in its calculations for CBCC by failing to include the depreciation expenses for all of CBCC's idle furnaces for all months of the POR. This was an error, petitioners state, because the final results notice says that the Department included depreciation expenses for idle assets in the total depreciation expenses. *See Fourth Review Final Results,* at 1980.

CBCC argues that the Department's calculation was proper because during part of the POR the furnaces in question were producing a product other than silicon metal. For the same reason CBCC argues further that if the Department decides to attribute depreciation for the furnaces at issue to silicon metal, it should attribute only part of it to silicon metal, and not all of it, as petitioners argue.

Department's Position: We agree with petitioners that for some months of the POR we failed to include depreciation for idle assets in total depreciation, which was a clerical error. We have corrected this error in these amended final results. We have allocated to the furnaces at issue a proportion of depreciation expenses equal to the volume of silicon metal produced by those furnaces relative to the volume of other products produced by those furnaces during the POR. *See* the amended final results analysis memorandum for our calculations.

Comment 17

Petitioners argue that the Department made a clerical error calculating Minasligas' variable overhead expenses. The Department, in order to allocate overhead costs to silicon metal, applied a ratio to Minasligas' total variable overhead amounts as given in exhibit 4 of Minasligas' October 15, 1996 supplemental questionnaire response. Petitioners argue that this was an error because the total variable overhead reported in exhibit 4 had already been allocated to silicon metal by Minasligas.

Department's Position: We agree, and have corrected this error in these amended final results.

Comment 18

Petitioners argue that the Department made a clerical error by not basing RIMA's charcoal costs on the price RIMA paid to its unaffiliated suppliers, and instead using the material costs RIMA reported in verification exhibit 7. In the final results the Department stated that it would base RIMA's charcoal costs on the prices it pays to its unaffiliated suppliers. *See Fourth Review Final Results,* at 1985.

RIMA argues that the costs reported in verification exhibit 7 are from unaffiliated suppliers, and that the Department therefore did not make a clerical error.

Department's Position: We agree with RIMA. The verification report says, ''By reviewing the documents pertaining to purchased charcoal, *e.g.,* the general ledger, supplier's invoices, and payment records, we confirmed that Rima's per-unit costs were based on the purchase price from third-party suppliers.'' *See* October 3, 1996 verification report, p. 12. Thus, our use of the charcoal costs contained in verification exhibit 7 does not constitute a clerical error.

Comment 19

Petitioners argue that the Department made a clerical error in its calculation of RIMA's imputed U.S. credit expenses. RIMA shipped each of its U.S. sales from its plant to the port of export in lots over a period of days, and reported to the Department the date of shipment for each lot. The Department stated in its final results analysis memorandum for RIMA that it used as the credit period the average number of days between the shipment date for each lot and the payment date. However, petitioners argue that the Department did not use the average credit period.

RIMA argues that the Department used an annual rate, and not a monthly rate, in its calculation of U.S. imputed credit expenses. Thus, RIMA argues, the Department should divide the rate used in the determination of imputed credit by 365 days, not 30 days.

Department's Position: We agree with petitioners that we did not use the average credit periods in the calculation of U.S. credit, although the final results analysis memorandum states the contrary. *See* July 24, 1997 RIMA final results analysis memorandum, p. 3. We have corrected this error in these amended final results. For our response to RIMA's argument that we should calculate credit using a denominator of 365, see our response to comment 9, above.

Comment 20

Eletrosilex argues that the Department made a ministerial error in its treatment of depreciation expenses. Eletrosilex argues that it explained in its submission that it had taken no depreciation in 1994 in order to compensate, as necessary under Brazilian accounting principles, for having taken accelerated depreciation in prior years, and that it had returned to normal depreciation in 1995. In comment 36 of the final results notice, the Department stated that evidence from Eletrosilex's financial statement indicates that its accounting of depreciation was not in accordance with Brazilian generally accepted accounting principles (GAAP). The Department therefore used the depreciation estimates given by Eletrosilex's independent auditor. Eletrosilex contends that the Department's determination that its accounting of depreciation was not in accordance with Brazilian GAAP constitutes a ministerial error. It argues that the financial statement made no determination as to whether Eletrosilex's accounting for depreciation was consistent with Brazilian GAAP in light of the earlier accelerated depreciation; it merely reflected the current year accounting. Eletrosilex argues that the Department mistakenly relied upon the financial statement out of context, instead of relying upon the actual data submitted by Eletrosilex and the explanation as to why no depreciation expense was shown for 1994.

Furthermore, Eletrosilex argues that the Department's recalculation of depreciation was flawed by exaggerating depreciation expense. The Department used one half of the audited depreciation expenses for all of 1994 and 1995. Eletrosilex argues that this method was doubly mistaken. First, the Department used numbers from the column designated as ''in currency with constant purchase power.'' Eletrosilex states that this column includes monetary adjustment, and therefore inflates the true number. Second, it double counts depreciation for 1995 because the depreciation expense is already included in fixed overhead.

Petitioners argue that the Department correctly determined that Eletrosilex's accounting of depreciation was not in accordance with Brazilian GAAP. It bases this argument on a statement contained in the report of the independent auditor which says that ''the company did not recognize . . . amounts corresponding to the depreciation of the fixed assets as required by the accounting principles foreseen in the CORPORATE'S LEGISLATION and by the main accounting principles.'' Therefore, petitioners argue, the Department was correct in not using the depreciation expenses that Eletrosilex reported to the Department.

Furthermore, petitioners argue that because Eletrosilex's 1994 financial statement did not contain any information about depreciation, the Department was obliged to use Eletrosilex's 1995 financial statement for information about Eletrosilex's depreciation for both 1994 and 1995. Thus, petitioners argue, the Department was justified in using the column ''in currency with constant purchase power'' for 1994 because that is how the information was presented in Eletrosilex's 1995 financial statement.

Finally, petitioners argue that information on the record indicates that the Department did not double count depreciation for all of the months that Eletrosilex claims it did.

Department's Position: We disagree with Eletrosilex that our calculation of depreciation is a clerical error. Rather, it is a methodological issue, and not a proper subject for review under the ministerial errors correction process. However, we do agree with Eletrosilex that we double counted depreciation for 1995. Therefore, in these amended final results of review we have corrected this error. *See* our amended final results analysis memorandum for our calculations.

Comment 21

Eletrosilex argues that the Department mistakenly disallowed an alleged short-term investment as an offset to its financial expenses because it incorrectly believed the claimed offset to be a capital gain. Eletrosilex argues that there is no basis for the Department so to interpret the transaction. It states that the claimed offset at issue was interest income accrued from bonds purchased as a short-term investment. The treatment of this short-term investment creating accrued interest is fully consistent, Eletrosilex argues, with the Department's traditional treatment of short-term interest as an offset to financial expenses, and the Department's treatment otherwise in the final results was based on a mistaken interpretation of the claim.

Petitioners argue that the Department made no ministerial error in its calculation of Eletrosilex's financial expenses. They argue that it is a respondent's responsibility to provide a detailed explanation of any claimed offset to expenses, and that Eletrosilex failed to meet this responsibility because it failed to provide the information necessary to distinguish interest income from capital gains. Furthermore, petitioners argue that the Department acted intentionally in denying this adjustment. Indeed, the Department specifically addressed the transaction in question in comment 5 of the final results notice. *See Fourth Review Final Results,* at 1974. Thus, petitioners argue, the Department's denial of this adjustment does not fit the regulatory definition of a clerical error, which is ''an error in addition, subtraction, or other arithmetic function, clerical error resulting from inaccurate copying, duplication, or the like, and any other type of unintentional error which the Secretary considers ministerial.'' 19 C.F.R. 353.28(d).

Department's Position: We agree with petitioners that our denial of this requested offset is not a clerical error. As reflected in the fourth review final results notice, we intended to deny this adjustment. *See Fourth Review Final Results* at 1974.

Comment 22

Eletrosilex argues that the Department erred by failing to grant a duty drawback adjustment. In the final results the Department denied this adjustment because Eletrosilex did not submit a claim for it until it submitted its case brief, subsequent to the 180-day regulatory deadline for submitting factual information. *See* 19 CFR § 353.31(a)(1)(ii). Eletrosilex argues that this decision unfairly distorted reality for no valid reason. It argues that the Department recognizes that mistakes occur, and has established the ''ministerial error'' provision for the purpose of correcting its own mistakes. Therefore, Eletrosilex argues, parties to proceedings should also be permitted to correct their mistakes where there is no prejudice or detriment to any of the parties. The oversight in question, Eletrosilex states, was just such an error. The Department's failure to correct the error, Eletrosilex argues, is an overly narrow interpretation which serves no purpose other than to punish Eletrosilex and increase a dumping margin for U.S. importers.

Petitioners argue that the Department made no ministerial error in denying Eletrosilex a duty drawback adjustment. The regulatory definition of ''ministerial error'' is ''an error in addition, subtraction, or other arithmetic function, clerical error resulting from inaccurate copying, duplication or the like, and any other type of unintentional error which the Secretary considers ministerial.'' *See* 19 CFR § 353.28(d). Furthermore, petitioners argue that the Department specifically addressed this issue in the final results. *See Fourth Review Final Results,* at 1988. Therefore, petitioners argue, the Department's denial of this adjustment was not a ministerial error.

Department's Position: We agree with petitioners that our denial of a duty drawback adjustment was not a ministerial error. It is a methodological issue, and not a proper subject for review under the ministerial errors correction process.

Comment 23

Eletrosilex argues that the Department used an incorrect amount for U.S. packing expenses. The final results analysis memorandum states that it used the packing expense that Eletrosilex submitted on its U.S. sales file. Eletrosilex argues that in the computer program the Department used a different amount.

Petitioners argue that the Department used the amount for packing that appears on Eletrosilex's U.S. sales file, and that therefore the Department did not make an error.

Department's Position: We disagree with Eletrosilex that we used the incorrect packing amount. *See* line 3805 of the final results program. We acknowledge, however, that our final results analysis memorandum incorrectly states that we used the figure that Eletrosilex submitted on its U.S. sales file. In the preliminary results, we recalculated Eletrosilex's packing figure based on the itemized packing costs Eletrosilex submitted because the figure it reported on its sales tape differed from the figure it reported in the narrative section of its questionnaire response. For our recalculations, see the September 3, 1996 Eletrosilex preliminary results analysis memorandum, p. 2. Thus, in neither the preliminary nor final results of review did we use the packing figure Eletrosilex submitted on its U.S. sales file, nor did we intend to do so. (In their comments on the preliminary results no party commented on the recalculation of packing.)

In addition to the changes made in the margin calculations in response to the above comments, we have also made the following changes to the programming in these amended final results:

- For Minasligas and Eletrosilex, we calculated U.S. imputed credit net of the ICMS tax assessed on the U.S. sale; and,
- For Eletrosilex, we used as the unit price of the U.S. sale the CIF value of the sale in U.S. dollars as given in exhibit 19 of Eletrosilex's October 25, 1995 submission.

Amended Final Results

As a result of our review, we have determined that the following margins exist for the period July 1, 1994 through June 30, 1995:

Producer/manufacturer/exporter	Weighted-average margin (percent)
CBCC	0.37
CCM	35.23
Eletrosilex	6.68
Minasligas	43.53
RIMA	51.23

The Department shall determine, and the U. S. Customs Service shall assess, antidumping duties on all appropriate entries. The Department shall issue appraisement instructions directly to the Customs Service.

Furthermore, the following deposit requirements shall be effective upon publication of this notice of amended final results of review for all shipments of silicon metal from Brazil entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided for by section 751(a)(1) of the Act: (1) the cash deposit rates for the reviewed companies named above will be the rates published in these amended final results; (2) for previously investigated or reviewed companies not listed above, the cash deposit rate will continue to be the company-specific rate published for the most recent period; (3) if the exporter is not a firm covered in these reviews, or the original less-than-fair-value (LTFV) investigations, but the manufacturer is, the cash deposit rate will be the rate established for the most recent period for the manufacturer of the merchandise; and (4) if neither the exporter nor the manufacturer is a firm covered in these reviews, the cash deposit rate will continue to be 91.06 percent, the ''all others'' rate established in the LTFV investigation. *See Final Determination of Sales at Less Than Fair Value: Silicon Metal from Brazil*, 56 FR 26977 (June 12, 1991).

This notice serves as a final reminder to importers of their responsibility under 19 CFR § 353.26 to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

This notice also serves as a reminder to parties subject to administrative protective order (''APO'') of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with section 353.34(d) of the Department's regulations. Timely notification of return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

These amended final results of review and notice are in accordance with section 751(a)(1) of the Act (19 U.S.C. § 1675(a)(1)) and section 353.28(c) of the Department's regulations.

Dated: October 14, 1997.

Robert S. LaRussa,

Assistant Secretary for Import Administration.

[FR Doc. 97–27632 Filed 10–16–97; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–351–806]

Silicon Metal From Brazil; Amended Final Results of Antidumping Duty Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Amended final results of antidumping duty administrative review.

SUMMARY: The Department of Commerce (the Department) is amending its final results of review, published on January 14, 1997, of the antidumping duty order on silicon metal from Brazil, to reflect the correction of ministerial errors in those final results. These amended final results are for the review covering the period July 1, 1993 through June 30, 1994.

EFFECTIVE DATE: October 17, 1997.

FOR FURTHER INFORMATION CONTACT: Fred Baker, Alain Letort, or John Kugelman, AD/CVD Enforcement Group III—Office 8, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, N.W., Washington, D.C. 20230, telephone 202/482–2924 (Baker), 202/482–4243 (Letort), or 202/482–0649 (Kugelman), fax 202/482–1388.

SUPPLEMENTARY INFORMATION:

Applicable Statute and Regulations

Unless otherwise indicated, all citations to the statute and to the regulations are references to the provisions as they existed on December 31, 1994.

Background

The Department published the final results of the third administrative review of the antidumping duty order on silicon metal from Brazil on January 14, 1997 (62 FR 1954) (*Third Review Final Results*), covering the period July 1, 1993 through June 30, 1994. The respondents are Companhia Brasileira Carbureto de Cálcio (CBCC), Companhia Ferroligas Minas Gerais—Minasligas (Minasligas), Eletrosilex Belo Horizonte (Eletrosilex), Rima Industrial S.A. (RIMA), and Camargo Corrêa Metais (CCM). The petitioners are American Alloys, Inc., Elken Metals, Co., Globe Metallurgical, Inc., SMI Group, and SKW Metals & Alloys.

On February 12, 1997, the petitioners filed clerical error allegations with respect to CCM and Minasligas. The same day we received clerical error allegations from respondent CCM. On February 18, 1997, we received rebuttal comments from the petitioners regarding CCM's clerical error allegations. Pursuant to the CIT's order, we are now addressing the ministerial allegations and amending our final results of the third review. *See American Silicon Technologies et al.*, v. *United States*, Slip Op. 97–114, August 18, 1997.

Scope of Review

The merchandise covered by this review is silicon metal from Brazil containing at least 96.00 percent but less than 99.99 percent silicon by weight. Also covered by this review is silicon metal from Brazil containing between 89.00 and 96.00 percent silicon by weight but which contains a higher aluminum content than the silicon metal containing at least 96.00 percent but less than 99.99 percent silicon by weight. Silicon metal is currently provided for under subheadings 2804.69.10 and 2804.50 of the Harmonized Tariff Schedule (HTS) as a chemical product, but is commonly referred to as a metal. Semiconductor grade silicon (silicon metal containing by weight not less than 99.99 percent silicon and provided for in subheading 2804.61.00 of the HTS) is not subject to the order. HTS item numbers are provided for convenience and for U.S. Customs purposes. The written description remains dispositive as to the scope of product coverage.

Clerical Error Allegations

Comment 1

CCM argues that the Department erred in its calculation of its U.S. imputed credit expenses in three ways. First, it argues that the Department should have

used CCM's ''actual credit'' expense, rather than an imputed figure. (The ''actual credit expense'' figure reported by CCM reflects the actual interest charged on its export credit line for its U.S. shipment.) CCM argues that this ''actual credit expense'' amount is the most accurate, transaction-specific measure of CCM's interest expense in connection with its U.S. sale. Second, CCM argues that if the Department continues to believe that it should use an imputed credit figure, it should use CCM's bill of lading date as the start of the credit period, rather than the date of shipment from CCM's factory. It bases this argument on the fact that title transfers from CCM to the U.S. purchaser on the bill of lading date. Thus, CCM argues, the credit period should begin on the bill of lading date because a credit expense cannot be incurred until CCM is no longer in possession of the merchandise. Third, CCM argues that the Department erred in its calculation of credit by not removing from the U.S. price the value of the ICMS tax (a value-added tax (VAT)) that the Brazilian government assessed on the sale. Doing so was an error, CCM argues, because in its response to comment 10 of the final results the Department stated that its practice ''is to calculate imputed credit exclusive of VAT.'' *See Third Review Final Results* at 1961.

Petitioners argue that the Department made no clerical error in calculating an imputed figure for CCM's credit expenses or in using the date of shipment from CCM's plant as the start of the credit period. They argue that the Department specifically addressed these issues in the final results of review when it stated:

> We disagree with CCM that we should use its reported ''actual expense'' for U.S. credit. The Department requires that the credit expenses reflect the opportunity cost of the entire period between shipment from the plant and payment by the customer. That is not the case for CCM's reported ''actual expense.'' The actual expense covers only a portion of the imputed credit expense period. Therefore, in these final results of review we have calculated imputed credit using the shipment date from CCM's plant as given in verification exhibit 11.

See Third Review Final Results at 1962.

Department's Position: We agree with both parties in part. We agree with petitioners that we did specifically address CCM's first two contentions in our final results of review. Thus, calculating an imputed credit figure and using the date of shipment from CCM's plant as the start of the credit period did not constitute clerical errors. However, we do agree with CCM that in the calculation of U.S. imputed credit we inadvertently included the ICMS tax assessed on the sale. We have corrected this error in these amended final results.

Comment 2

Petitioners argue that the Department made a ministerial error in the cost test for CCM. It states that the Department made a number of changes to CCM's reported costs, and that when it made these changes it gave the revised costs the variable name COP. However, when the Department performed the cost test, petitioners argue, it used the variable TOTCOP, which represents CCM's reported costs without any of the intended changes.

Department's Position: We agree, and have corrected this error in these amended final results of review.

Comment 3

Petitioners argue the Department made a clerical error in its calculation of Minasligas' G&A expenses. It argues that the Department incorrectly transcribed the G&A expenses for one month of the period of review (POR).

Department's Position: We agree, and have corrected this error in these amended final results of review.

Comment 4

Petitioners argue that the Department made a clerical error in converting Minasligas' brokerage, foreign inland freight, and warehousing expenses from Brazilian cruzeiros reais into U.S. dollars. They argue that the Department should have used the exchange rates of the dates of shipment for these expenses, rather than the exchange rates of the dates of sale.

Department's Position: We agree, and have corrected this error in these amended final results of review.

In addition to the changes made in response to the above comments, we have corrected an error in our calculations for all respondents with calculated margins. In our final results, we calculated G&A and interest expenses for the computation of COP/CV using a COM figure inclusive of VAT. In these amended final results we have calculated G&A and interest expenses using a COM figure exclusive of VAT. *See* our amended final results analysis memoranda for our revised calculations.

Amended Final Results of Review

As a result of this review, we have determined that the following margins exist for the period July 1, 1993 through June 30, 1994:

Producer/manufacturer/exporter	Weighted-average margin (percent)
CBCC	61.58
CCM	35.23
Eletrosilex	38.39
Minasligas	0.00
RIMA	91.06

The Department shall determine, and the U.S. Customs Service shall assess, antidumping duties on all appropriate entries. The Department shall issue appraisement instructions directly to the Customs Service.

Furthermore, the following deposit requirements shall be effective upon publication of this notice of amended final results of review for all shipments of silicon metal from Brazil entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided for by section 751(a)(1) of the Act: (1) the cash deposit rates for the reviewed companies named above will be the rates published in the amended final results of review for the antidumping duty order on silicon metal from Brazil for the period July 1, 1994 through June 30, 1995, published concurrently with this notice; (2) for previously investigated or reviewed companies not listed above, the cash deposit rate will continue to be the company-specific rate published for the most recent period; (3) if the exporter is not a firm covered in these reviews, or the original less-than-fair-value (LTFV) investigation, but the manufacturer is, the cash deposit rate will be the rate established for the most recent period for the manufacturer of the merchandise; and (4) if neither the exporter nor the manufacturer is a firm covered in these reviews, the cash deposit rate will continue to be 91.06 percent, the ''all others'' rate established in the LTFV investigation. *See Final Determination of Sales at Less Than Fair Value: Silicon Metal from Brazil,* 56 FR 26977 (June 12, 1991).

This notice serves as a final reminder to importers of their responsibility under 19 CFR § 353.26 to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

This notice also serves as a reminder to parties subject to administrative protective order (''APO'') of their responsibility concerning the

disposition of proprietary information disclosed under APO in accordance with section 353.34(d) of the Department's regulations. Timely notification of return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

These amended final results of review and notice are in accordance with section 751(a)(1) of the Act (19 U.S.C. § 1675(a)(1)) and section 353.28(c) of the Department's regulations.

Dated: October 10, 1997.

Robert S. LaRussa,

Assistant Secretary for Import Administration.

[FR Doc. 97–27633 Filed 10–16–97; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

South Pacific Tuna Act of 1988; Proposed Collection; Comment Request

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)).

DATES: Written comments must be submitted on or before December 16, 1997.

ADDRESSES: Direct all written comments to Linda Engelmeier, Departmental Forms Clearance Officer, Department of Commerce, Room 5327, 14th and Constitution Avenue, NW, Washington DC 20230.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument(s) and instructions should be directed to Dan Viele, National Marine Fisheries Service, 501 W. Ocean Blvd., Long Beach, CA 90802, (562–980–4039).

SUPPLEMENTARY INFORMATION:

I. Abstract

The Treaty on Fisheries Between the Governments of Certain Pacific Island States and the Government of the United States of America, signed in Port Moresby, Papua New Guinea, in 1987, and its annexes, schedules and implementing agreements, as amended (Treaty), authorizes U.S. tuna vessels to fish within fishing zones of a large region of the Pacific Ocean. The South Pacific Tuna Act (16 U.S.C. 973g and 973j) and U.S. implementing regulations (50 CFR 282.3 and 282.5) authorize the collection of information from participants in the Treaty fishery.

Vessel operators who wish to participate in the Treaty fishery must submit annual license and registration applications and periodic written reports of catch and unloading of fish from a licensed vessel. The information collected is submitted to the Forum Fisheries Agency (FFA) on forms supplied by the FFA through the U.S. government (National Marine Fisheries Service [NMFS]). License and registration application information is used by FFA to determine the operational capability and financial responsibility of a vessel operator interested in participating in the Treaty fishery. Information obtained from vessel catch and unloading reports is used by FFA to assess fishing effort and fishery resources in the region and to track the amount of fish caught within each Pacific island state's exclusive economic zone for fair disbursement of Treaty monies. If the information is not collected, the U.S. government will not meet its obligations under the Treaty, and the lack of fishing information will result in poor management of the fishery resource.

II. Method of Collection

The information is collected using the forms required under the Treaty.

III. Data

OMB Number: 0648–0218.
Form Number: N/A.
Type of Review: Regular Submission.
Affected Public: Businesses (respondents are the operators of U.S. commercial tuna purse seine vessels participating in the Treaty fishery).
Estimated Number of Respondents: Approximately 32 vessels are expected to participate in the fishery during each year the Treaty is in effect, however, the number may vary.
Estimated Time Per Response: The estimated response times for the reporting requirements are: .25 hours for a license application form; .25 hours for a registration application form; 1 hour for a catch report form; and .5 hours for an unloading log sheet.
Estimated Total Annual Burden Hours: The estimated total annual burden has decreased from 337 hours to 248 hours due to a decrease in the number of respondents and responses.
Estimated Total Annual Cost to Public: $576 for mailing costs.

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: October 9, 1997.

Linda Engelmeier,

Departmental Forms Clearance Officer, Office of Management and Organization.

[FR Doc. 97–27525 Filed 10–16–97; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

Evaluation of Coastal Zone Management Program and National Estuarine Research Reserves

AGENCY: Office of Ocean and Coastal Resource Management, National Ocean Service, National Oceanic and Atmospheric Administration (NOAA), DOC.

ACTION: Notice of intent to evaluate.

SUMMARY: The NOAA Office of Ocean and Coastal Resource Management (OCRM) announces its intent to evaluate the performance of Hawaii and New Jersey Coastal Zone Management Programs and the Chesapeake Bay National Estuarine Research Reserve in Maryland.

These evaluations will be conducted pursuant to sections 312 and 315 of the Coastal Zone Management Act of 1972 (CZMA), as amended. The CZMA requires a continuing review of the performance of states with respect to coastal program or estuarine research reserve program implementation. Evaluation of Coastal Zone Management and Estuarine Research Reserve Programs require findings concerning the extent to which a state has met the national objectives, adhered to its

coastal program document or final management plan approved by the Secretary of Commerce, and adhered to the terms of financial assistance awards funded under the CZMA. The evaluations will include a site visit, consideration of public comments, and consultations with interested Federal, State, and local agencies and members of the public. Public meetings are held as part of the site visits.

Notice is hereby given of the dates of the site visits for the listed evaluations, and the dates, local times, and locations of public meetings during the site visits

The Hawaii Coastal Zone Management Program site visit will be from December 8–12, 1997. One public meeting will be held during the week. This meeting is scheduled for 7:00 p.m., Thursday, December 11, 1997, at the State Capitol Auditorium (on the basement level by the parking garage entrance beneath Beretania Street entrance), Honolulu, Hawaii.

The New Jersey Coastal Zone Management Program site visit will be from December 8–12, 1997. Two public meetings will be held during the week. The meetings are scheduled for 7:30 p.m., on Tuesday, December 9, 1997, at Monmouth University, McGill Commons Clubroom, Rooms 107 & 108, Cedar Avenue, West Long Branch, New Jersey and for 7:30 p.m., on Thursday, December 11, 1997, at the Cape May City Municipal Building, Auditorium, 643 Washington Street, Cape May City, New Jersey.

The Chesapeake Bay National Estuarine Research Reserve in Maryland site visit will be from November 17–21, 1997. Two public meetings will be held during the week. The meetings are scheduled for 7:30 p.m., Tuesday, November 18, 1997, at the Patuxent River 4–H Center, 18405 Queen Anne Road, Upper Marlboro, Maryland, and for 7:30 p.m., Wednesday, November 19, 1997, at the Anita C. Leight Estuary Center, Leight Park, 700 Otter Point Road, Abingdon, Maryland.

The States will issue notice of the public meeting(s) in a local newspaper(s) at least 45 days prior to the public meeting(s), and will issue other timely notices as as appropriate.

Copies of the State's most recent performance reports, as well as OCRM's notifications and supplemental request letters to the States, are available upon request from OCRM. Written comments from interested parties regarding these Programs are encouraged and will be accepted until 15 days after the public meeting. Please direct written comments to Vickie A. Allin, Chief, Policy Coordination Division (PCD), Office of Ocean and Coastal Resource Management, NOS/NOAA, 1305 East-West Highway, Silver Spring, Maryland, 20910. When the evaluation is completed, OCRM will place a notice in the **Federal Register** announcing the availability of the Final Evaluation Findings.

FOR FURTHER INFORMATION CONTACT: Vickie A. Allin, Chief, Policy Coordination Division, Office of Ocean and Coastal Resource Management, NOS/NOAA, 1305 East-West Highway, Silver Spring, Maryland, 20910, (301) 713–3090, ext. 126.

Federal Domestic Assistance Catalog 11.419 Coastal Zone Management Program Administration

Dated: October 10, 1997.

Captain Evelyn Fields,

Acting Deputy Assistant, Administrator for Ocean Services and Coastal Zone Management.

[FR Doc. 97–27546 Filed 10–16–97; 8:45 am]

BILLING CODE 3510–08–M

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D.091797C]

Marine Mammals; Scientific Research Permit No. 878–1410

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Issuance of permit.

SUMMARY: Notice is hereby given that Dr. Daniel F. Cowan, Professor of Pathology, The University of Texas Medical Branch, Galveston, Texas 77555–0555, has been issued a permit to import and export marine mammal specimens for scientific purposes.

ADDRESSES: The permit and related documents are available for review upon written request or by appointment. (see **SUPPLEMENTARY INFORMATION**)

SUPPLEMENTARY INFORMATION: On August 7, 1997, notice was published in the **Federal Register** (62 FR 44251) that a request for a scientific research permit to import and export marine mammal specimen materials had been submitted by the above-named individual. The requested permit has been issued under the authority of the Marine Mammal Protection Act of 1972, as amended (16 U.S.C. 1361 *et seq.*) and the Regulations Governing the Taking and Importing of Marine Mammals (50 CFR part 216), the Endangered Species Act of 1973 (ESA, 16 U.S.C. 1531 *et seq.*), the regulations governing the taking, importing and exporting of endangered fish and wildlife (50 CFR 222.23), and the Fur Seal Act of 1966 (16 U.S.C. 1151 *et seq.*).

Issuance of this permit as required by the ESA is based on a finding that such permit: (1) Was applied for in good faith: (2) Will not operate to the disadvantage of the endangered species which are the subject of this permit: and (3) is consistent with the purposes and policies set forth in Section 2 of the ESA.

Addresses:

Documents are available in the following offices: Permits Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13130, Silver Spring, MD 20910 (301/713–2289);

Northeast Region, NMFS, One Blackburn Drive, Gloucester, MA 01930–2289 (508/281–9250);

Southeast Region, NMFS, 9721 Executive Center Drive North, St. Petersburg, FL 33702–2432 (813/570–5301);

Southwest Region, NMFS, 501 West Ocean Blvd., Suite 4200, Long Beach, CA 90802–4213 (310/980–4001);

Northwest Region, NMFS, 7600 Sand Point Way, NE, BIN C15700, Bldg., 1, Seattle, WA 98115–0070 (206/526–6150); and

Alaska Region, NMFS, P.O. Box 21668, Juneau, AK 99802–1668 (907/586–7221).

Dated: October 8, 1997.

Ann D. Terbush,

Chief, Permits and Documentation Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 97–27520 Filed 10–16–97; 8:45 am]

BILLING CODE 3510–22–F

CONSUMER PRODUCT SAFETY COMMISSION

Sunshine Act Meeting

AGENCY: Consumer Product Safety Commission.

TIME AND DATE: 10:00 a.m., Wednesday, October 22, 1997.

LOCATION: Room 420, East West Towers, 4330 East West Highway, Bethesda, Maryland.

STATUS: Open to the Public.

MATTER TO BE CONSIDERED:

FY 1998 Operating Plan

The staff will brief the Commission on issues related to the Commission's Operating Plan for Fiscal Year 1998.

For a recorded message containing the latest agenda information, call (301) 504–0709.

CONTACT PERSON FOR ADDITIONAL INFORMATION: Sadye E. Dunn, Office of the Secretary, 4330 West Highway, Bethesda, MD 20207 (301) 504–0800.

Dated: October 15, 1997.

Sadye E. Dunn,

Secretary.

[FR Doc. 97–27737 Filed 10–15–97; 2:31 pm]

BILLING CODE 6355–01–M

DEPARTMENT OF DEFENSE

Department of the Air Force

Record of Decision (ROD) for the Disposal and Reuse of Plattsburgh Air Force Base (AFB), New York

On October 2, 1997, the Air Force issued a Record of Decision (ROD) for the Disposal and Reuse of Plattsburgh AFB, New York. The decisions included in this ROD have been made in consideration of, but not limited to, the information contained in the Final Environmental Impact Statement (FEIS) for the Disposal and Reuse of Plattsburgh AFB, filed with the Environmental Protection Agency and made available to the public on November 9, 1995.

Plattsburgh AFB closed on September 25, 1995, pursuant to the Defense Base Closure and Realignment Act of 1990 (10 U.S.C. § 2687 note) and the recommendations of the Defense Base Closure and Realignment Commission. The FEIS analyzed potential environmental impacts of the Air Force's disposal options by portraying a variety of potential land uses to cover a range of reasonably foreseeable future uses of the property and facilities by others. This ROD supplements the Partial ROD (PROD) the Air Force issued on August 21, 1996, which documented a number of decisions regarding the intended disposal of Government-owned property at the base. It announced that the base would be disposed of in parcels, described the parcels, and identified the methods of disposal for some of the parcels. It also discussed possible environmental impacts and mitigations. Disposal decisions for the remainder of the former base were deferred.

This ROD addresses the methods of disposal for real property not addressed in the PROD. That portion of the former base located west of U. S. Route 9, referred to as the ''New Base,'' for which disposal decisions were not announced in the PROD, will be made available for disposal through a public airport conveyance (approximately 3,070 acres of improved land). That portion of the base located east of U. S. Route 9, referred to as the ''Old Base,'' for which disposal decisions were not announced in the PROD, will be made available for disposal through an Economic Development Conveyance (approximately 250 acres). Both of the disposal decisions are subject to eligible applicants submitting approvable applications by December 31, 1998. After that date, the respective property would be offered for disposal by sale. The ROD also addresses what actions, if any, the Air Force will take to avoid or mitigate adverse environmental consequences from its disposal actions, if different from those described in the PROD.

The implementation of these conversion activities and associated mitigation measures will proceed with minimal adverse impact to the environment. This action conforms with applicable Federal, State and local statutes and regulations, and all reasonable and practical efforts have been incorporated to minimize harm to the local public and the environment.

Any questions regarding this matter should be directed to Mr. John Carr, Program Manager, (703) 696–5546. Correspondence should be sent to: AFBCA/DA, 1700 North Moore Street, Suite 2300, Arlington, VA 22209–2802.

Barbara A. Carmichael,

Alternate Air Force Federal Register Liaison Officer.

[FR Doc. 97–27607 Filed 10–16–97; 8:45 am]

BILLING CODE 3910–01–P

DEPARTMENT OF DEFENSE

Department of the Air Force

Intent to Grant an Exclusive Patent License

Pursuant to the provisions of Part 404 of Title 37, Code of Federal Regulations, which implements Public Law 96–517, the Department of the Air Force announces its intention to grant Tel Med Technologies (hereafter TMT), a Michigan Corporation, an exclusive license, under United States Patent Application Serial No. 08/581/795 filed in the name of Stephen M. Schmitt for a ''Method of Fabricating Precise Cast or Noncast Implant-Retained Dental Restorations Using Electrical Discharge Machining.''

The license described above will be granted unless an objection thereto, together with a request for an opportunity to be heard, if desired, is received in writing by the addressee set forth below within sixty (60) days from the date of publication of this Notice. Information concerning the application may be obtained, on request, from the same addressee.

All communications concerning this Notice should be sent to: Mr. Randy Heald, Patent Attorney, Secretary of the Air Force, Office of the General Counsel, SAF/GCQ, 1501 Wilson Blvd., Suite 805, Arlington, VA 22209–2403, telephone (703) 696–9037.

Barbara A. Carmichael,

Alternate Air Force Federal Register Liaison Officer.

[FR Doc. 97–27606 Filed 10–16–97; 8:45 am]

BILLING CODE 3910–01–P

DEPARTMENT OF DEFENSE

Department of the Army

Exclusive License Announcement: U.S. Army Research Laboratory

ACTION: Notice.

SUMMARY: In accordance with 37 CFR 404.7(a)(1)(I), announcement is made of prospective exclusive license of U.S. Patent 5,617,031, ''Buried Pipe Locator Utilizing a Change in Ground Capacitance,'' for the purpose of manufacturing, using, and selling a product for buried pipe and cable finder.

This invention is described as a buried pipe detection device based upon the principle of sensing of differences in the dielectric/conductive properties of the ground in the vicinity of where the pipe is disclosed. The right to this United States Patent is owned by the United States of America, as represented by the Secretary of the Army. Under the authority of section 11(a)(2) of the Federal Technology Transfer Act of 1986 (Pub. L. 99–502) and section 207 of title 35 United States Code, the Department of the Army, as represented by the U.S. Army Research Laboratory, intends to grant a limited term exclusive license of the above mentioned patent to Charles Machine Works, Inc., 1959 West Fir Avenue, Perry, Oklahoma, represented by, General Manager, Subsite Electronics, 1950 W. Fir, Perry, Oklahoma, for buried pipe and cable finder.

FOR FURTHER INFORMATION CONTACT: Ms. Norma Vaught, Technology Transfer Office, AMSRL–CS–TT, U.S. Army Research Laboratory, Adelphi, MD 20783–1197; tel: (301) 394–2952; fax (301) 394–5815; e-mail: nvaught@arl.mil.

SUPPLEMENTARY INFORMATION: Pursuant to 37 CFR 404.7(a)(1)(I), any interested party may file written objections to this prospective exclusive license arrangement. Written objections should

be directed to the above address on or before 60 days from the publication of this notice.

Mary V. Yonts,

Alternate Army Federal Register Liaison Officer.

[FR Doc. 97–27536 Filed 10–16–97; 8:45 am]

BILLING CODE 3710–08–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. TM98–1–84–001]

Caprock Pipeline Company; Notice of Proposed Changes in FERC Gas Tariff

October 10, 1997.

Take notice that on October 8, 1997, Caprock Pipeline company (Caprock) tendered for filing as part of its FERC Gas Tariff, First Revised Volume No. 1, the following revised Tariff sheets, to be effective October 1, 1997:

Substitute Sixth Revised Sheet No. 4
Substitute Sixth Revised Sheet No. 5

Caprock states that these substitute Tariff sheets are being submitted to comply with the Commission's September 29, 1997 Order in this proceeding.

Caprock states that copies of the filing were served upon Caprock's jurisdictional customers, interested public bodies, and all parties to the proceedings.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, in accordance with Section 385.211 of the Commission's Rules of Practice and Procedure. All such protests must be filed as provided in Section 154.210 of the Commission's Regulations. All protests filed with the Commission will be considered by it in determining the appropriate action to be taken, but will not serve to make the protestants parties to the proceeding. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 97–27562 Filed 10–16–97; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP97–406–000]

CNG Transmission Corporation; Notice of Technical Conference

October 10, 1997.

In the Commission's order issued July 31, 1997, the Commission held that, if necessary, the Staff may convene a technical conference to address issues raised by comments on CNG's supplemental filing concerning changes to its terms and conditions of service.

Take notice that the technical conference will be held on Friday, October 31, 1997 at 9:00 a.m., in a room to be designated at the offices of the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426. All interested parties and Staff are permitted to attend.

Lois D. Cashell,

Secretary.

[FR Doc. 97–27558 Filed 10–16–97; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP98–6–000]

Dauphin Island Gathering Partners; Notice of Application

October 10, 1997.

Take notice that on October 3, Dauphin Island Gathering Partners (DIGS), c/o OEDC, Inc., 1400 Woodloch Forest Drive, Suite 200, the Woodlands, Texas 77380, filed in Docket Nos. CP98–6–000 an application, pursuant to Section 7(c) of the Natural Gas Act and Section 157 of thy Commission's Regulations, for a certificate of public convenience and necessity to construct facilities to implement the second phase of a two-stage construction project to attach offshore supplies to an onshore delivery point near Coden, Louisiana. Specifically, DIGS proposes to (1) construct and operate approximately 13 miles of 24-inch pipeline extending from Alabama state waters at State Tract 73 to a proposed processing facility near Coden, Alabama, and (2) abandon a temporary interconnection located in Alabama State Tract 73 between DIGS existing facilities and DIGS' 65-mile pipeline authorized to be constructed by DIGS in Docket No. CP97–300–000, and for approval of *pro forma* tariff sheets providing for negotiated rates for both firm and interruptible services, and other tariff modifications, all as more fully set forth in the applications, which are on file with the Commission and open for public inspection.

DIGS states that, in its application filed in Docket No. CP97–300–000, it proposed to construct its system in two stages, with authorization sought in that application only for the first phase. DIGS indicated that the Phase I facilities would extend from Main Pass Block 225 to Alabama State Tract 73 (MP facilities). DIGS also stated that, pending completion of the Phase II facilities, which are being proposed in this application, the Phase I facilities would interconnect temporarily with existing facilities that extend from Block 73 onshore to Coden, Alabama (the DI facilities) where gas would be delivered to the systems of interstate pipeline companies.

DIGS estimates a construction cost of the proposed facilities of $19,368,716, which would be financed from cash on hand from the various partners of DIGS.

DIGS has included *pro forma* tariff sheets with its application as First Revised Volume No. 1 to its tariff setting forth the rate schedules, general terms and conditions and forms of service agreements that would be provided if the requested certificate is granted. It is indicated the proposed tariff would replace the Original Volume No. 1 of the tariff filed on September 2, 1997, in compliance with the June 27, 1997, order approving the Phase I facilities. It is also stated that the proposed tariff reflects separate service for the DI facility in that, after Phase II is completed, Dauphin Island's DI facilities and MP facilities will no longer be connected and will ship gas of different qualities. DIGS states that as a result, different quality specifications are set forth for the transportation of rich gas through the MP facilities and lean gas through the DI facilities.

DIGS states that the Commission's June 27, 1997, order permitted DIGS to charge and collect a recourse rate of $0.1756 for Rate Schedule FT–1 and further authorized DIGS to charge negotiated rates for service under Rate Schedules FT–2 and FT–3. It is indicated that the June 27, 1997, order stated that the Commission would review DIGS' rate methodology when DIGS filed its certificate application for the Phase II facilities. DIGS now proposes to modify its methodology to reflect that it will be operating two separate jurisdictional facilities because of different operational requirements related to the rich versus lean nature of the two gas streams and assertion of Commission jurisdiction over facilities previously operated as gathering

facilities. DIGS now proposes to establish a separate recourse rate for each facility to reflect that discrete DIGS facilities will be operated independently of each other. DIGS indicates that the recourse rate for each facility will be the applicable FT–1 rate. DIGS also proposes to continue to collect negotiated rates under Rate Schedules FT–2 and FT–3. Also, DIGS for the first time proposes negotiated rates for interruptible service.

Any person desiring to participate in the hearing process or to make any protest with reference to said application should on or before October 31, 1997, file with the Federal Energy Regulatory Commission, Washington, D.C. 20426, a motion to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a motion to intervene in accordance with the Commission's Rules.

A person obtaining intervenor status will be placed on the service list maintained by the Secretary of the Commission and will receive copies of all documents filed by the applicant and by every one of the intervenors. An intervenor can file for rehearing of any Commission order and can petition for court review of such order. However, an intervenor must submit copies of comments or any other filing it makes with the Commission to every other intervenor in the proceeding as well as 14 copies with the Commission.

A person does not have to intervene, however, in order to have comments considered. A person, instead, may submit two copies of comments to the Secretary of the Commission. Commenters will be placed on the Commission's environmental mailing list, will receive copies of environmental documents and will be able to participate in meetings associated with the Commission's environmental review process. Commenters will not be required to serve copies of filed documents on all other parties. However, commenters will not receive copies of all documents filed by other parties or issued by the Commission and will not have the right to seek rehearing or appeal the Commission's final order to a federal court.

The Commission will consider all comments and concerns equally, whether filed by commenters or those requesting intervenor status.

Take further notice that, pursuant to the authority contained in and subject to the jurisdiction conferred upon the Federal Energy Regulatory Commission by Sections 7 and 15 of the Natural Gas Act and the Commission's Rules of Practice and Procedure, a hearing will be held without further notice before the Commission or its designee on this application if no motion to intervene is filed within the time required herein, if the Commission on its own review of the matter finds that a grant of the certificate and permission and approval for the proposed abandonment are required by the public convenience and necessity. If a motion for leave to intervene is timely filed, or if the Commission on its own motion believes that a formal hearing is required, further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for DIGS to appear or be represented at the hearing.

Lois D. Cashell,

Secretary.

[FR Doc. 97–27552 Filed 10–16–97; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. TM98–1–53–001]

K N Interstate Gas Transmission Co.; Notice of Proposed Changes In FERC Gas Tariff

October 10, 1997.

Take notice that on October 8, 1997, K N Interstate Gas Transmission Co. (KNI) tendered for filing as part of its FERC Gas Tariff, the following revised tariff sheets, to become effective October 1, 1997:

Third Revised Volume No. 1–A

Substitute Fourth Revised Sheet No. 4–D

First Revised Volume No. 1–C

Substitute Ninth Revised Sheet No. 4

KNI states that these substitute tariff sheets are being submitted to comply with the Commission's September 29, 1997 Order in this proceeding.

KNI states that copies of the filing were served upon KNI's jurisdictional customers, interested public bodies, and all parties to the proceeding.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, in accordance with Section 385.211 of the Commission's Rules of Practice and Procedure. All such protests must be filed as provided in Section 154.210 of the Commission's Regulations. All protests filed with the Commission will be considered in determining the appropriate action to be taken, but will not serve to make the protestants parties to the proceeding. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 97–27561 Filed 10–16–97; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP98–9–000]

Koch Gateway Pipeline Company; Notice of Request Under Blanket Authorization

October 10, 1997.

Take notice that on October 7, 1997, Koch Gateway Pipeline Company (Koch Gateway), P.O. Box 1478, Houston, Texas 77251–1478, filed in Docket No. CP98–9–000 a request pursuant to §§ 157.205, 157.211 and 157.216 of the Commission's Regulations under the Natural Gas Act (18 CFR 157.205, 157.211 and 157.216) for authorization to abandon 10 delivery taps and establish six new delivery taps in Mobile County, Alabama, under Koch Gateway's blanket certificate issued in Docket No. CP82–430, pursuant to Section 7 of the Natural Gas Act, all as more fully set forth in the request that is on file with the Commission and open to public inspection.

Koch Gateway proposes to abandon ten farm taps on its Index 276 transmission pipeline in Mobile County, Alabama. In addition. Koch Gateway proposes to install six taps and minor piping to tie over certain taps to its adjacent Index 300 pipeline facilities or to the facilities of Mobile Gas Service Corporation (MGS), a local distribution company. Koch Gateway states that these taps are used for delivery of natural gas to end-users on behalf of MGS, and that MGS concurs with the proposed abandonment and tie-over measures.

Koch Gateway states that no abandonment of service is proposed herein, and that it will continue to provide transportation service on a firm

basis to these relocated taps. Koch Gateway estimates the cost of the proposed abandonment and construction activities to be $46,000 and states that the purchaser of the Index 276 pipeline will reimburse Koch Gateway for all such costs.

Any person or the Commission's staff may, within 45 days after issuance of the instant notice by the Commission, file pursuant to Rule 214 of the Commission's Procedural Rules (18 CFR 385.214) a motion to intervene or notice of intervention and pursuant to § 157.205 of the Regulations under the Natural Gas Act (18 CFR 157.205) a protest to the request. If no protest is filed within the time allowed therefor, the proposed activity shall be deemed to be authorized effective the day after the time allowed for filing a protest. If a protest is filed and not withdrawn within 30 days after the time allowed for filing a protest, the instant request shall be treated as an application for authorization pursuant to Section 7 of the Natural Gas Act.

Lois D. Cashell,

Secretary.

[FR Doc. 97–27555 Filed 10–16–97; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER94–1247–015]

NORAM Energy Services, Inc.; Notice of Filing

October 10, 1997.

Take notice that on August 28, 1997, NORAM Energy Services, Inc., tendered for filing its compliance filing in the above-referenced docket.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 18 CFR 385.214). All such motions or protests should be filed on or before October 20, 1997. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 97–27556 Filed 10–16–97; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP98–7–000]

Northern Natural Gas Company; Notice of Request Under Blanket Authorization

October 10, 1997.

Take notice that on October 3, 1997, Northern Natural Gas Company (Northern), 1111 South 103rd Street, Omaha, Nebraska 68124–1000, filed in Docket No. CP98–7–000 a request pursuant to §§ 157.205, 157.212 and 157.216 of the Commission's Regulations under the Natural Gas Act (18 CFR 157.205, 157.212 and 157.216) for authorization to upgrade the Marquette #1A and Negaunee #1 town border stations in Marquette County, Michigan, under Northern's blanket certificate issued in Docket No. CP82–401–000 pursuant to Section 7 of the Natural Gas Act, all as more fully set forth in the request that is on file with the Commission and open to public inspection.

Northern proposes to upgrade the two existing delivery points by replacing the existing meters, regulators and associated piping. Northern estimates that the peak day and annual volumes to be delivered to SEMCO Energy Gas Company (SEMCO) are 9,612 MMBtu and 982,346 MMBtu at the Marquette #1A and 3,748 MMBtu and 383,046 MMBtu at the Negaunee #1. Deliveries of the estimated volumes will be made pursuant to Northern's currently effective throughput service agreements with SEMCO. Northern states that SEMCO requested the proposed delivery point upgrades to accommodate a growth of natural gas requirements in the respective areas. The total estimated cost to upgrade is $130,000.

Northern states that the proposed activity is not prohibited by its existing tariff, that it has sufficient capacity to accomplish deliveries without detriment or disadvantage to its other customers and that the total volumes delivered after the request will not exceed total volumes authorized prior to the request.

Any person or the Commission's staff may, within 45 days after issuance of the instant notice by the Commission, file pursuant to Rule 214 of the Commission's Procedural Rules (18 CFR 385.214) a motion to intervene or notice of intervention and pursuant to § 157.205 of the Regulations under the Natural Gas Act (18 CFR 157.205) a protest to the request. If no protest is filed within the time allowed therefor, the proposed activity shall be deemed to be authorized effective the day after the time allowed for filing a protest. If a protest is filed and not withdrawn within 30 days after the time allowed for filing a protest, the instant request shall be treated as an application for authorization pursuant to Section 7 of the Natural Gas Act.

Lois D. Cashell,

Secretary.

[FR Doc. 97–27553 Filed 10–16–97; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP97–129–008]

Questar Pipeline Company; Notice of Tariff Filing

October 8, 1997.

Take notice that on October 2, 1997, Questar Pipeline Company (Questar) tendered for filing as part of its FERC Gas Tariff, First Revised Volume No. 1, the below-listed tariff sheets to be effective November 1, 1997:

Proposed Tariff Sheets

Original Sheet Nos. 46C, 81B and 84A
First Revised Sheet Nos. 75A, 99A, 99B, 99C and 99D
Second Revised Sheet Nos. 43, 46B, 75B, 75C, 80A, 81A and 84
Third Revised Sheet Nos. 44 and 75
Fourth Revised Sheet Nos. 45 and 46A
Sixth Revised Sheet No. 46

Questar states that the filing is being made in compliance with the September 24, 1997, OPR Director Letter Order in Docket No. RP97–129–003.

Questar states that the proposed tariff sheets implement the requirements of Order No. 587–C and comply with the Commission's September 24 directive to (1) correct a typographical error in Standard 2.3.31 and (2) revise the tariff language that incorporates GISB Standard 2.3.9.

Questar states further that a copy of this filing has been served upon its customers, the Public Service Commission of Utah and the Wyoming Public Service Commission.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission,

888 First Street, N.E., Washington, D.C. 20426, in accordance with Section 385.211 of the Commission's Rules of Practice and Procedure. All such protests must be filed in accordance with Section 154.210 Commission's Regulations. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 97–27563 Filed 10–16–97; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP97–526–000]

Southern Natural Gas Company; Notice of Site Visit

October 10, 1997.

On October 14, 1997, beginning at 8:30 a.m., the Office of Pipeline Regulation staff will conduct a pre-certificate inspection of the facilities proposed by Southern Natural Gas Company (Southern) for its East Tennessee Expansion Project. The inspection will originate from Southern's office at 1900 Fifth Avenue North, Birmingham, Alabama, and proceed to proposed facility locations in Perry County, Alabama; Spalding, Henry, Clayton, Fulton, Floyd, and Catoosa Counties, Georgia; and Hamilton County, Tennessee.

All parties may attend. Those planning to attend must provide their own transportation.

For further information, please contact Paul McKee at (202) 208–1088.

Robert J. Cupina,

Deputy Director, Office of Pipeline Regulation.

[FR Doc. 97–27550 Filed 10–16–97; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP98–5–000]

Texas Eastern Transmission Corporation; Notice of Application

October 10, 1997.

Take notice that on October 2, 1997, Texas Eastern Transmission Corporation (TETCO), 5400 Westheimer Court, Houston, Texas 77056–5310 filed in Docket No. CP98–5–000 an application pursuant to Section 7(b) and 7(c) of the Natural Gas Act for permission and approval for TETCO to construct and operate certain replacement facilities in Harrison County, Texas and to abandon by removal certain facilities being replaced all as more fully set forth in the application on file with the Commission and open to public inspection.

TETCO states that it has been informed by Texas Eastman, Division of Eastman Chemical Company (Eastman), an industrial chemical plant and right-of-way grantor, of Eastman's proposed rail yard expansion in Harrison County, Texas, which is being undertaken to alleviate capacity restrictions in Eastman's operations. TETCO asserts that Eastman has requested that TETCO expedite the relocation and lowering of TETCO's 20-inch Line No. 13, which crosses Eastman's property. TETCO indicates that the replacement will be offset 35 feet to the northeast of the existing pipeline and approximately 3.51 acres of land and one landowner, in addition to Eastman, are to be affected by the proposed relocation.

Specifically, TETCO proposes to replace, construct, own and operate approximately 598 feet of 20-inch mainline in Harrison County, Texas and to abandon by removal the existing 20-inch pipeline segments to be replaced. TETCO estimates the total capital cost of the replacement to be $701,000 and states that it will be reimbursed 100% for the project by Eastman.

Any person desiring to participate in the hearing process or to make any protest with reference to said application should on or before October 31, 1997, file with the Federal Energy Regulatory Commission, Washington, D.C. 20426, a motion to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a motion to intervene in accordance with the Commission's Rules.

A person obtaining intervenor status will be placed on the service list maintained by the Secretary of the Commission and will receive copies of all documents filed by the applicant and by every one of the intervenors. An intervenor can file for rehearing of any Commission order and can petition for court review of any such order. However, an intervenor must submit copies of comments or any other filing it makes with the Commission to every other intervenor in the proceeding, as well as 14 copies with the Commission.

A person does not have to intervene, however, in order to have comments considered. A person, instead, may submit two copies of comments to the Secretary of the Commission. Commenters will be placed on the Commission's environmental mailing list, will receive copies of environmental documents and will be able to participate in meetings associated with the Commission's environmental review process. Commenters will not be required to serve copies of filed documents on all other parties. However, commenters will not receive copies of all documents filed by other parties or issued by the Commission and will not have the right to seek rehearing or appeal the Commission's final order to a federal court.

The Commission will consider all comments and concerns equally, whether filed by commenters or those requesting intervenor status.

Take further notice that, pursuant to the authority contained in and subject to jurisdiction conferred upon the Federal Energy Regulation Commission by Sections 7 and 15 of the Natural Gas Act and the Commission's Rules of Practice and Procedure, a hearing will be held without further notice before the Commission or its designee on this application if no motion to intervene is filed within the time required herein, if the Commission on its own review of the matter finds that a grant of the authorization is required by the public convenience and necessity. If a motion for leave to intervene is timely filed, or if the Commission on its own motion believes that a formal hearing is required, further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for TETCO to appear or be represented at the hearing.

Lois D. Cashell,

Secretary.

[FR Doc. 97–27551 Filed 10–16–97; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP97–344–000]

Texas Gas Transmission Corporation; Notice of Informal Settlement Conference

October 10, 1997.

Take notice that an informal settlement conference will be convened in this proceeding on Tuesday, October 28, 1997, at 1:30 p.m. and Wednesday, October 29, 1997, at 10:00 a.m., at the offices of the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, for the purposes of exploring the possible settlement of the above-referenced docket.

Any party, as defined by 18 CFR 385.102(c), or any participant as defined in 18 CFR 385.102(b), is invited to attend. Persons wishing to become a party must move to intervene and receive intervenor status pursuant to the Commission's regulations (18 CFR 385.214).

For additional information, please contact Kathleen M. Dias at (202) 208-0524 or Michael D. Cotleur at (202) 208-1076.

Lois D. Cashell,

Secretary.

[FR Doc. 97–27557 Filed 10–16–97; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP98–8–000]

Transwestern Pipeline Company; Notice of Request Under Blanket Authorization

October 10, 1997.

Take notice that on October 3, 1997, Transwestern Pipeline Company (Transwestern), P.O. Box 3330, Omaha, Nebraska 68103–0330, filed in Docket No. CP98–8–000 a request pursuant to §§ 157.205 and 147.212 of the Commission's Regulations (18 CFR 157.205 and 157.212) under the Natural Gas Act (NGA) for authorization to operate existing facilities in Coconino County, Arizona, as a delivery point under Transwestern's blanket certificate issued in Docket No. CP82–534–000, pursuant to Section 7 of the NGA, all as more fully set forth in the request that is on file with the Commission and open to public inspection.

Transwestern proposes to utilize the facilities for deliveries of natural gas to Citizens Utility Company (CUC), which has requested the delivery point to serve residential customers. It is asserted that Transwestern will use the facilities to deliver up to 250 MMBtu equivalent of gas on a peak day to CUC and 36,500 MMBtu on an annual basis. It is asserted that the proposal is not prohibited by Transwestern's existing tariff and can be accomplished without detriment or disadvantage to Transwestern's other customers. It is further asserted that the total volumes delivered to CUC to not exceed the volumes authorized prior to the request.

Any person or the Commission's staff may, within 45 days after issuance of the instant notice by the Commission, file pursuant to Rule 214 of the Commission's Procedural Rules (18 CFR 385.214) a motion to intervene or notice of intervention and pursuant to § 157.205 of the Regulations under the Natural Gas Act (18 CFR 157.205) a protest to the request. If no protest is filed within the time allowed therefor, the proposed activity shall be deemed to be authorized effective the day after the time allowed for filing a protest. If a protest is filed and not withdrawn within 30 days after the time allowed for filing a protest, the instant request shall be treated as an application for authorization pursuant to Section 7 of the Natural Gas Act.

Lois D. Cashell,

Secretary.

[FR Doc. 97–27554 Filed 10–16–97; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. TM98–1–52–000]

Western Gas Interstate Company; Notice of Proposed Changes in FERC Gas Tariff

October 10, 1997.

Take notice that on September 26, 1997, Western Gas Interstate Company (WGI) tendered for filing as part of its FERC Gas Tariff, Fourth Revised Volume No. 1, Third Revised Sheet no. 10, to be effective October 1, 1997.

WGI states that the purpose of this filing is to increase its Annual Charge Adjustment (ACA) unit rate from $0.0020 to $0.0022. The ACA rate is designed to recover the annual charge assessed by the Commission pursuant to Part 382 of the Regulations.

WGI states that copies of the filing were served upon its customers and interested state commissions.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C., in accordance with Section 385.211 of the Commission's Rules and Regulations. All such protests must be filed in accordance with Section 154.210 of the Commission's Regulations. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make the protestants parties to the proceeding. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room.

Lois D. Cashell,

Secretary.

[FR Doc. 97–27560 Filed 10–16–97; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER97–4691–000, et al.]

Montaup Electric Company, et al.; Electric Rate and Corporate Regulation Filings

October 9, 1997.

Take notice that the following filings have been made with the Commission:

1. Montaup Electric Company

[Docket No. ER97–4691–000]

Take notice that on September 19, 1997, Montaup Electric Company (Montaup), tendered for filing amendments to its open access transmission tariff to provide for (a) pass-through of any NEPOOL ancillary services charges not billed directly to the customer and (b) a formula for determining transmission revenue requirements. Montaup requests waiver of the notice requirements so that the amendments may become effective July 1, 1997.

Comment date: October 23, 1997, in accordance with Standard Paragraph E at the end of this notice.

2. Pennsylvania Power & Light Company

[Docket No. ER97–4692–000]

Take notice that on September 22, 1997, Pennsylvania Power & Light Company (PP&L), filed a Service Agreement dated September 16, 1997, with Market Responsive Energy, Inc. (MREI), under PP&L's FERC Electric Tariff, Original Volume No. 1. The Service Agreement adds MREI as an eligible customer under the Tariff.

PP&L requests an effective date of September 22, 1997, for the Service Agreement.

PP&L states that copies of this filing have been supplied to MREI and to the Pennsylvania Public Utility Commission.

Comment date: October 23, 1997, in accordance with Standard Paragraph E at the end of this notice.

3. Orange and Rockland Utilities, Inc.

[Docket No. ER97–4693–000]

Take notice that on September 22, 1997, Orange and Rockland Utilities, Inc. (Orange and Rockland), filed a Service Agreement between Orange and Rockland and Sonat Power Marketing L.P., (Customer). This Service Agreement specifies that Customer has agreed to the rates, terms and conditions of Orange and Rockland Open Access Transmission Tariff filed on July 9, 1996 in Docket No. OA96–210–000.

Orange and Rockland requests waiver of the Commission's sixty-day notice requirements and an effective date of September 4, 1997, for the Service Agreement. Orange and Rockland has served copies of the filing on The New York State Public Service Commission and on the Customer.

Comment date: October 23, 1997, in accordance with Standard Paragraph E at the end of this notice.

4. Duquesne Light Company

[Docket No. ER97–4694–000]

Take notice that on September 22, 1997, Duquesne Light Company (DLC), filed a Service Agreement dated September 16, 1997, with Williams Energy Services Co., under DLC's Open Access Transmission Tariff (Tariff). The Service Agreement adds Williams Energy Services Co., as a customer under the Tariff. DLC requests an effective date of September 16, 1997, for the Service Agreement.

Comment date: October 23, 1997, in accordance with Standard Paragraph E at the end of this notice.

5. Duquesne Light Company

[Docket No. ER97–4695–000]

Take notice that on September 22, 1997, Duquesne Light Company (DLC), filed a Service Agreement dated September 16, 1997, with MidCon Power Services Corp., under DLC's Open Access Transmission Tariff (Tariff). The Service Agreement adds MidCon Power Services Corp., as a customer under the Tariff. DLC requests an effective date of September 16, 1997, for the Service Agreement.

Comment date: October 23, 1997, in accordance with Standard Paragraph E at the end of this notice.

6. Kansas City Power & Light Company

[Docket No. ER97–4696–000]

Take notice that on September 22, 1997, Kansas City Power & Light Company (KCPL), tendered for filing a Service Agreement dated September 18, 1997, between KCPL Transmission Services and KCPL Power Sales & Services. KCPL proposes an effective date of September 18, 1997, and requests a waiver of the Commission's notice requirement to allow the requested effective date. This Agreement provides for the rates and charges for Short-term Firm Transmission Service.

In its filing, KCPL states that the rates included in the above-mentioned Service Agreement are KCPL's rates and charges in the compliance filing to FERC Order No. 888–A in Docket No. OA97–636–000.

Comment date: October 23, 1997, in accordance with Standard Paragraph E at the end of this notice.

7. Consolidated Edison Company of New York, Inc.

[Docket No. ER97–4697–000]

Take notice that on September 22, 1997, Consolidated Edison Company of New York, Inc. (Con Edison), tendered for filing, pursuant to its FERC Electric Tariff Rate Schedule No. 2, a service agreement for Central Hudson Gas and Electric Corp., to purchase electric capacity and energy pursuant at negotiated rates, terms, and conditions.

Con Edison states that a copy of this filing has been served by mail upon Central Hudson Gas and Electric Corp.

Comment date: October 23, 1997, in accordance with Standard Paragraph E at the end of this notice.

8. Duquesne Light Company

[Docket No. ER97–4698–000]

Take notice that on September 22, 1997, Duquesne Light Company (DLC) filed a Service Agreement dated September 16, 1997, with Equitable Power Services Co., under DLC's Open Access Transmission Tariff (Tariff). The Service Agreement adds Equitable Power Services Co., as a customer under the Tariff. DLC requests an effective date of September 16, 1997, for the Service Agreement.

Comment date: October 23, 1997, in accordance with Standard Paragraph E at the end of this notice.

9. Duquesne Light Company

[Docket No. ER97–4699–000]

Take notice that on September 22, 1997, Duquesne Light Company (DLC) filed a Service Agreement dated September 4, 1997, with e prime, Inc., under DLC's Open Access Transmission Tariff (Tariff). The Service Agreement adds e prime, Inc., as a customer under the Tariff. DLC requests an effective date of September 4, 1997, for the Service Agreement.

Comment date: October 23, 1997, in accordance with Standard Paragraph E at the end of this notice.

10. Duquesne Light Company

[Docket No. ER97–4700–000]

Take notice that on September 22, 1997, Duquesne Light Company (DLC) filed a Service Agreement dated September 4, 1997, with e prime, Inc., under DLC's FERC Coordination Sales Tariff (Tariff). The Service Agreement adds e prime, Inc., as a customer under the Tariff. DLC requests an effective date of September 4, 1997, for the Service Agreement.

Comment date: October 23, 1997, in accordance with Standard Paragraph E at the end of this notice.

11. Sierra Pacific Power Company

[Docket No. ER97–4701–000]

Take notice that on September 22, 1997, Sierra Pacific Power Company (Sierra), tendered for filing a Service Agreement (Service Agreement) with ConAgra Energy Services, Inc., for Non-Firm Point-to-Point Transmission Service under Sierra's Open Access Transmission Tariff (Tariff):

Sierra filed the executed Service Agreement with the Commission in compliance with Section 14.4 of the Tariff and applicable Commission regulations. Sierra also submitted revised Sheet Nos. 148 and 148A (Attachment E) to the Tariff, which is an updated list of all current subscribers. Sierra requests waiver of the Commission's notice requirements to permit and effective date of August 25, 1997, for Attachment E, and to allow the Service Agreement to become effective according to its terms.

Copies of this filing were served upon the Public Service Commission of Nevada, the Public Utilities Commission of California and all interested parties.

Comment date: October 23, 1997, in accordance with Standard Paragraph E at the end of this notice.

12. Louisville Gas and Electric Company

[Docket No. ER97–4702–000]

Take notice that on September 22, 1997, Louisville Gas and Electric Company, tendered for filing copies of service agreements between Louisville Gas and Electric Company and Electric Clearinghouse, Inc., under Rate GSS.

Comment date: October 23, 1997, in accordance with Standard Paragraph E at the end of this notice.

13. Florida Power Corporation

[Docket No. ER97–4703–000]

Take notice that on September 22, 1997, Florida Power Corporation (Florida Power), tendered for filing a service agreement between Tennessee Valley Authority and Florida Power for service under Florida Power's Market-Based Wholesale Power Sales Tariff (MR–1), FERC Electric Tariff, Original Volume No 8. This Tariff was accepted for filing by the Commission on June 26, 1997, in Docket No. ER97–2846–000. The service agreement is proposed to be effective September 9, 1997.

Comment date: October 23, 1997, in accordance with Standard Paragraph E at the end of this notice.

14. Rochester Gas and Electric Corporation

[Docket No. ER97–4704–000]

Take notice that on September 22, 1997, Rochester Gas and Electric Corporation (RG&E) filed a Service Agreement between RG&E and the Virginia Electric and Power Company (Customer). This Service Agreement specifies that the Customer has agreed to the rates, term and conditions of RG&E's FERC Electric Rate Schedule, Original Volume No. 1 (Power Sales Tariff) accepted by the Commission in Docket No. ER94–1279–000, as amended by RG&E's December 31, 1996, filing in Docket No. OA97–243–000 (pending).

RG&E requests waiver of the Commission's sixty (60) day notice requirements and an effective date of September 5, 1997, for the Virginia Electric and Power Company Service Agreement. RG&E has served copies of the filing on the New York State Public Service Commission and on the Customer.

Comment date: October 23, 1997, in accordance with Standard Paragraph E at the end of this notice.

15. Rochester Gas and Electric Corporation

[Docket No. ER97–4705–000]

Take notice that on September 22, 1997, Rochester Gas and Electric Corporation (RG&E) filed a Service Agreement between RG&E and the New Energy Ventures Inc.(Customer). This Service Agreement specifies that the Customer has agreed to the rates, terms and conditions of the RG&E open access transmission tariff filed on July 9, 1996 in Docket No. OA96–141–000.

RG&E requests waiver of the Commission's sixty (60) day notice requirements and an effective date of September 15, 1997, for the New Energy Ventures Inc. Service Agreement. RG&E has served copies of the filing on the New York State Public Service Commission and on the Customer.

Comment date: October 23, 1997, in accordance with Standard Paragraph E at the end of this notice.

Standard Paragraph

E. Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 18 CFR 385.214). All such motions or protests should be filed on or before the comment date. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 97–27588 Filed 10–16–97; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Amendment to License

October 10, 1997.

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. Application Type: Amendment to License.

b. Project No: 2833–057.

c. Date Filed: September 3, 1997.

d. Applicant: Public Utility District No. 1 of Lewis County.

e. Name of Project: Cowlitz Falls Hydroelectric Project.

f. Location: The project is located on the Cowlitz River just below its confluence with the Cispus River in Lewis County, Washington.

g. Filed Pursuant to: 18 CFR § 4.200.

h. Applicant Contact: Mr. Gary Kalish, Public Utility District No. 1 of Lewis County, P.O. Box 330, Chehalis, WA 98532, (360) 740–2411.

i. FERC Contact: Steve Hocking (202) 219–2656.

j. Comment Date: December 5, 1997.

K. Description of Amendment: Public Utility District No. 1 of Lewis County (licensee) filed an application to amend its approved fish and wildlife mitigation plan for the Cowlitz Falls Hydroelectric Project. The licensee requests Commission approval of a land-swap already approved by the Washington Department of Fish and Wildlife. The licensee proposes substituting land in the newly designated Kiona Wildlife Management Unit (80.6 acres) for land in Wildlife Management Units No. 7 and 8 (37 acres total) that must be acquired pursuant to its approved fish and wildlife mitigation plan. The application would amend the plan with other minor changes as well.

This notice also consists of the following standard paragraphs: B, C1, and D2.

B. Comments, Protests, or Motions to Intervene—Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

C1. Filing and Service of Responsive Documents—Any filings must bear in all capital letters the title ''COMMENTS'', ''RECOMMENDATIONS FOR TERMS AND CONDITIONS'', ''PROTEST'', OR ''MOTION TO INTERVENE'', as applicable, and the Project Number of the particular application to which the filing refers. Any of the above-named documents must be filed by providing the original and the number of copies provided by the Commission's regulations to: The Secretary, Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426. A copy of any motion to intervene must also be served upon each representative of the Applicant specified in the particular application.

D2. Agency Comments—Federal, state, and local agencies are invited to file comments on the described application. A copy of the application may be obtained by agencies directly from the Applicant. If an agency does not file comments within the time specified for filing comments, it will be presumed to have no comments. One copy of an agency's comments must also

be sent to the Applicant's representatives.

Lois D. Cashell,

Secretary.

[FR Doc. 97–27559 Filed 10–16–97; 8:45 am]

BILLING CODE 6717–01–M

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–5485–3]

Environmental Impact Statements; Notice of Availability

Responsible Agency: Office of Federal Activities, General Information (202) 564–7167 OR (202) 564–7153.

Weekly receipt of Environmental Impact Statements Filed October 06, 1997 Through October 10, 1997 Pursuant to 40 CFR 1506.9.

EIS No. 970390, Draft Supplement, USA, MS, Camp Shelby Continued Military Training Activities, Use of National Forest Lands, Updated Information, Final Site Selection Authorization for Implementation of the Proposed G.V. (Sonny) Montgomery Ranges, Special Use Permit, DeSoto National Forest, Forrest, George and Perry Counties, MS, Due: December 01, 1997, Contact: Col. Parker Hills (601) 973–6349.

EIS No. 970391, Draft EIS, FHW, NY, US–20/Broadway (Transit Road to Lancaster East Village Line) Reconstruction, Funding, COE Section 10 and 404 Permit, in the Villages of Depew and Lancaster, Erie County, NY, Due: December 12, 1997, Contact: Harold J. Brown) (518) 472–3616.

EIS No. 970392, Final EIS, BOP, KY, United States Penitentiary Martin County, Construction and Operation, Possible Sites, Bizwell and Honey Branch Sites, located in Martin and Johnson Counties, KY, Due: November 17, 1997, Contact: David J. Dorworth (202) 514–6470.

EIS No. 970393, Final EIS, IBR, ND, Arrowwood National Wildlife Refuge, Implementation, Water Management Capability to Mitigate for Past, Present and Future Impacts of Jamestown Reservoir, Stutsman and Foster Counties, ND, Due: November 17, 1997, Contact: Greg Hiemenz (701) 250–4242 Ext. 361.

EIS No. 970394, Draft EIS, AFS, CA, Liberty Forest Health Improvement Project, Implementation, Tahoe National Forests, Sierraville Ranger District, Sierra and Nevada Counties, CA, Due: December 01, 1997, Contact: Phil Horning (916) 478–6210.

EIS No. 970395, Final EIS, NPS, AZ, Organ Pipe Cactus National Monument General Management Plan and Development Concept Plan Implementation, Portion of the Sonoran Desert, Pima County, AZ, Due: November 17, 1997, Contact: Dan Olson (415) 744–3968.

EIS No. 970396, Final EIS, COE, MD, WV, Jennings Randolph Lake 1997 Master Plan Update and Integrated Programmatic EIS—Use and Development of Natural and Constructed Resource, Garrett County, MD and Mineral County, WV, Due: November 18, 1997, Contact: Ms. Heather Wells (410) 962–5174.

EIS No. 970397, Final EIS, AFS, NH, Waterville Valley Ski Resort Project, Development of Snowmaking Water Impoundments Project, Special-Use-Permits, Dredge and Fill Permit and COE Section 404 Permit, White Mountain National Forest, Pemigewasset Ranger District, Town of Waterville Valley, Grafton County, NH, Due: November 17, 1997, Contact: Beth LeClair (802) 767–4261.

EIS No. 970398, Final Supplement, EPA, TX, South Hallsville Surface Lignite No. 1 Mine Expansion, Referred to Herein as South Marshall Project Area, (Previously Known as Henry W. Pirkey Power Plant and South Hallsville No. 1 Mine Project), Updated Information NPDES and COE Section 404 Permits, Sabine River, Harrison County, TX, Due: November 17, 1997, Contact: Joe Swick (214) 665–7456.

EIS No. 970399, Final EIS, AFS, UT, High Uintas Wilderness Forest Plan Amendment, Implementation, Ashley and Wasatch-Cache National Forests, Duchesne and Summit Counties, UT, Due: November 17, 1997, Contact: Laura Jo West (801) 789–1181.

EIS No. 970400, Draft EIS, COE, CA, South Sacramento County Streams Investigation, Proposed to Increase Flood Protection, Non-Federal Sponsor, Sacramento Waste Water Treatment Plant and along portions of Morrison, Elder, Unionhouse and Florin Creeks, Sacramento County, CA, Due: December 01, 1997, Contact: Jane Rinck (916) 557–6715.

Dated: October 14, 1997.

B. Katherine Biggs,

Associate Director, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 97–27627 Filed 10–16–97; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–5485–4]

Environmental Impact Statements and Regulations; Availability of EPA Comments

Availability of EPA comments prepared September 15, 1997 through September 20, 1997 pursuant to the Environmental Review Process (ERP), under Section 309 of the Clean Air Act and Section 102(2)(c) of the National Environmental Policy Act as amended. Requests for copies of EPA comments can be directed to the Office of Federal Activities at (202) 564–7167.

An explanation of the ratings assigned to draft environmental impact statements (EISs) was published in FR dated April 11, 1997 (62 FR 16154).

Draft EISs

ERP No. D–AFS–J65276–CO Rating EC2, Dome Peak Timber Sale, Timber Harvesting and Road Construction, White River National Forest, Eagle Ranger District, Glenwood Spring, Eagle and Garfield Counties, CO.

Summary: EPA expressed environmental concerned about potential sedimentation and water quality impacts. EPA requested data clarifying potential for impacts and information related to helicopter yarding and wildlife impacts.

ERP No. D–AFS–K65272–CA Rating EC2, Chico Genetic Resource Center for Pest Management Program, Implementation, Mendocino National Forest, Willow, Butte County, CA.

Summary: EPA expressed environmental concern about data gaps in the DEIS's analysis of water quality impacts.

ERP No. D–AFS–K65273–AZ Rating LO, Grand Canyon/Tusayan Growth Area Improvements, General Management Plan (GMP), Special-Use-Permit, Approvals and Licenses Issuance, Coconino County, AZ.

Summary: EPA expressed a lack of objections and commended the Forest Service for its excellent analysis of issues related to the expansion of lodging and related services.

ERP No. D-BLM-K67045-NV Rating EC2, Florida Canyon Mine Expansion Project and Comprehensive Reclamation Plan, Construction and Operation of New Facilities and Expansion of Existing Gold Mining Operations in Imlay Mining District, Plan-of-Operation Approval and Right-of-Way Permit Issuance, Pershing County, NV.

Summary: EPA expressed environmental concerns because the Proposed Alternative would disturb 143

acres more than another alternative assessed in the DEIS, and the DEIS did not clearly indicate which action alternative is the least environmentally damaging to aquatic resources under Clean Water Act Section 404. EPA also expressed concerns regarding how the site was geochemically characterized and offered recommendations for facility design and additional monitoring.

ERP No. D-DOA-G31002-TX Rating LO, Bexar-Medina-Atascosa Counties Water Conservation Plan, Renovation and Installation, Funding, Medina Lake, Bexar, Medina and Atascosa Counties, TX.

Summary: EPA had no objection to the selection of the lead agency's preferred alternative as described in the draft EIS.

ERP No. D-DOE-C06013-NY Rating LO, Disposal of the Defueled S3G and D1G Prototype Reactor Plants, Implementation, Located at the Knolls Atomic Power Laboratory Kesselring Site near West Milton, Saratoga County, NY.

Summary: EPA had no objection to the action as proposed.

ERP No. D–IBR–K28018–CA Rating EC2, Central Valley Project, Municipal and Industrial Water Supply Contracts, Sacramento County Water Agency and San Juan Water District, City of Folsom, Sacramento County, CA.

Summary: EPA expressed environmental concerns with the identified additional adverse cumulative impacts of the proposed new water supply diversions, and urged selection of diversion points on the Sacramento River below the confluence with the American River or as far downstream on the American River as feasible.

EPA expressed support for water conservation, water pricing strategies, water reclamation, conjunctive use, and other demand reduction measures as means to achieving additional water supply. EPA suggested a more aggressive water conservation approach as part of the proposed action, integration of other demand reduction measures, and continued pursuit of conservation alternatives (e.g. metering, water reclamation), whether or not new contract water is provided.

ERP No. D–ICC–G53007–LA Rating EC2, Kansas City Southern Railway (KCS) Construction and Operation to Connect the Geismar Industrial Area to KCS' Mainline near Sorrento, Construction Exemption Approval, Ascension Parish, LA.

Summary: EPA expressed environmental concerns for the lead agency's preferred alternative and requests additional information, environmental justice alternatives analysis, and cumulative impacts assessment.

Final EISs

ERP No. F–FHW–E40759–AL Birmingham Northern Beltline Project, Construction, I–59/20 west to I–59 northeast in the City of Birmingham, Funding and Possible COE Section 404 Permit, Jefferson County, AL.

Summary: EPA's review revealed that all alternatives will have major impacts on environmental resources in the highway corridor. EPA recommends that the shortest alternative, ''D'', be reconsidered with modification.

ERP No. F–FHW–J40212–CO CO–82 Highway Transportation Project, Improvements to ''Entrance to Aspen'', Funding and COE Section 404 Permit, City of Aspen, Pitkin County, CO.

Summary: EPA's review has not identified any potential environmental impacts requiring substantive changes to the Preferred Alternative.

ERP No. F–FTA–C40137–NY Wassaic Extension Project, Expand Metro-North, Funding and Right-of-Way, Dutchess and Litchfield Counties, NY.

Summary: EPA believed that the proposed project would not result in significant adverse environmental impacts, and therefore, has no objections to its implementation.

Dated: October 14, 1997.

B. Katherine Biggs,

Associate Director, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 97–27628 Filed 10–16–97; 8:45 am]

BILLING CODE 6560–50–U

ENVIRONMENTAL PROTECTION AGENCY

[FRL–5910–5]

Common Sense Initiative Council (CSIC)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notification of Public Advisory CSI Council Meeting, and the CSI Petroleum Refining and Printing Sector Subcommittee Meetings; open meetings.

SUMMARY: Pursuant to the Federal Advisory Committee Act, Pub. L. 92–463, notice is hereby given that the CSI Council Meeting and the CSI Petroleum Refining and Printing Sector Subcommittees of the Common Sense Initiative Council will meet on the dates and times described below. All meetings are open to the public. Seating at all three meetings will be on a first-come basis and limited time will be provided for public comment. For further information concerning specific meetings, please contact the individuals listed with the three announcements below.

(1) Common Sense Initiative Council Meeting—November 3 and 4, 1997

The Common Sense Initiative Council will hold an open meeting on Monday, November 3, 1997 from 1:00 p.m. EST to 6:00 p.m. EST, and on Tuesday, November 4, 1997 from 8:30 a.m. to 3:00 p.m. EST. The meeting will be held at the George Washington University Club and Conference Center, 800 21st Street, N. W., Washington, D.C. 20062, telephone (202) 994–6611.

The Council Agenda will focus on a variety of topics including: A report from the Reinventing Environment Information (REI) Council workgroup on the Agency's draft Implementation Plan; an update on the Center for Environmental Information and Statistics; a request for approval of the Metal Finishing Sector Subcommittee's Strategic Goals 2000 Program; presentation of the Print Sector Subcommittee's Comprehensive Strategy for an Alternative Multi-Media Flexible Permit System; an Agency report on the status of the Iron and Steel, Auto, and Metal Finishing Sector Subcommittees' recommendations that were approved and forwarded to EPA at the July Council meeting; Sector Guidance and a strategic approach and work plan for the Council; as well as documentation of the Computer and Electronics Sector Subcommittee's Consolidated Uniform Report on the Environment (CURE) Stakeholder Needs Assessment, and the final white paper on Consensus Decision-making Principles and Applications in CSI.

For further information concerning this Common Sense Initiative Council meeting, contact Kathleen Bailey, DFO on (202) 260–7417, or E-mail: bailey.kathleen@epamail.epa.gov.

(2) Petroleum Refining Sector Subcommittee Meeting—November 4–5, 1997

Notice is hereby given that the Environmental Protection Agency will hold an open meeting of the Common Sense Initiative (CSI) Petroleum Refining Sector Subcommittee on November 4 and 5, 1997. Work Group meetings will be held from 9:00 a.m. EST to 12:00 noon EST on Tuesday, November 4. The full Subcommittee will meet from approximately 2:00 p.m. EST until 5:00 p.m. EST on Tuesday, November 4, and from approximately 8:00 a.m. EST until 4:00 p.m. EST on Wednesday, November 5. The meeting

will be held at the Madison Hotel, 15th and M Streets, NW, Washington, DC 20005. The hotel telephone number is 202–862–1600.

The Subcommittee meeting agenda includes a discussion of compliance issues for the petroleum refining industry, a presentation on accidents and worker safety issues, and an update on the status of the One Stop Reporting and Public Access Project and the Equipment Leaks Project. The Subcommittee also plans to discuss potential new project ideas. A public comment period has been scheduled from approximately 2:00 p.m. EST until 3:00 p.m. EST on Wednesday, November 5, 1997.

For further information concerning this meeting of the Petroleum Refining Sector Subcommittee, please contact either Craig Weeks, Designated Federal Officer (DFO), at US EPA Region 6 (6EN), 1445 Ross Avenue, Dallas, TX 75202–2733, by telephone at 214–665–7505 or E-mail at weeks.craig@epamail.epa.gov or Steve Souders, Alternate DFO, at US EPA by mail (5306W), 401 M Street, SW, Washington, DC 20460, by telephone at 703–308–8431 or E-mail at souders.steve@epamail.epa.gov.

(3) Printing Sector Subcommittee—November 6, 1997

Notice is hereby given that the Environmental Protection Agency will hold an open meeting of the Printing Sector Subcommittee on Thursday, November 6, 1997, from approximately 1:00 p.m. EST until 4:00 p.m. EST. The New York City Education Project Team (NYCEP) and the Alternative Multi-Media Flexible Permit Project Team (MFP) will hold meetings the previous day, Wednesday, November 5, 1997, from approximately 9:00 a.m. EST until 5:00 p.m. EST, and if needed on November 6 from 1:30 p.m. EST to 3:30 p.m. EST. The Meetings will be held at the Washington National Airport Hilton, located at 2399 Jefferson Davis Highway in Crystal City, VA, Telephone number (703) 418–6800.

The Printing Sector Subcommittee will hear reports from its two project teams, the Alternative Multi media Flexible Permit Project Team and the New York City Education Project Team.

The Alternative Multi media Flexible Permit Project Team will report on its presentation to the Common Sense Initiative Council planned for November 4. This team is approaching the final stages of crafting an alternative permit system that leads to reduced emissions, greater operational flexibility, enhanced public involvement, and lower transaction costs. The New York City Education Project Team will report on progress implementing its model outreach program. NYCEP coordinates state and local technical assistance providers and community interest groups as partners in promoting environmentally sound printing practices to neighborhood printers.

For further information concerning meeting times and agenda of this Printing Sector Subcommittee meeting, please contact either Frank Finamore, Designated Federal Officer (DFO), at EPA, by telephone on (202) 564–7039, or Mick Kulik, Alternate DFO, at EPA Region 3 in Philadelphia, PA on (215) 566–5337.

Inspection of Subcommittee Documents

Documents relating to the above Sector Subcommittee announcements, will be publicly available at the meeting. Thereafter, these documents, together with the official minutes for the meetings, will be available for public inspection in room 2821M of EPA Headquarters, Common Sense Initiative Staff, 401 M Street, SW, Washington, DC 20460, telephone number 202–260–7417. Common Sense Initiative information can be accessed electronically on our web site at http.//www.epa.gov/commonsense.

Dated: October 14, 1997.

Kathleen Bailey,

Designated Federal Officer.

[FR Doc. 97–27623 Filed 10–16–97; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–5910–4]

Notice of Proposed Purchaser Agreement Pursuant to the Comprehensive Environmental Response, Compensation and Liability Act of 1980, as Amended by the Superfund Amendments and Reauthorization Act

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice; request for public comment.

SUMMARY: In accordance with the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as amended by the Superfund Amendments and Reauthorization Act of 1986 (CERCLA), 42 U.S.C. 9601–9675, notice is hereby given that a proposed purchaser agreement (Purchaser Agreement) associated with the Kane and Lombard Superfund Site in Baltimore, Maryland was executed by the Environmental Protection Agency and the Department of Justice and is now subject to public comment, after which the United States may modify or withdraw its consent if comments received disclose facts or considerations which indicate that the Purchaser Agreement is inappropriate, improper, or inadequate. The Purchaser Agreement would resolve certain potential EPA claims under section 107 of CERCLA, 42 U.S.C. 9607, against Double Eagle Enterprises, Inc. (Purchaser). The settlement would require the Purchaser to, among other things, pay $1500.00 within thirty (30) days of the effective date of the Purchaser Agreement to the EPA Hazardous Substances Superfund and abide by certain land use restrictions intended to protect the integrity of surface and subsurface structures installed by EPA in accordance with a CERCLA Record of Decision issued by EPA in September 1987.

For thirty (30) days following the date of publication of this document, the Agency will receive written comments relating to the proposed Purchaser Agreement. The Agency's response to any comments received will be available for public inspection at the U.S. Environmental Protection Agency, Region III, 841 Chestnut Building, Philadelphia, PA 19107.

DATES: Comments must be submitted on or before November 17, 1997.

Availability

The proposed Purchaser Agreement and additional background information relating to the proposed Purchaser Agreement are available for public inspection at the U.S. Environmental Protection Agency, Region III, 841 Chestnut Building, Philadelphia, PA 19107. A copy of the proposed Purchaser Agreement may be obtained from Suzanne Canning, U.S. Environmental Protection Agency, Regional Docket Clerk (3RC00), 841 Chestnut Building, Philadelphia, PA 19107. Comments should reference the ''Kane and Lombard Superfund Site Prospective Purchaser Agreement'' and ''EPA Docket No. III–97–82-DC,'' and should be forwarded to Suzanne Canning at the above address.

FOR FURTHER INFORMATION CONTACT: Andrew S. Goldman (3RC21), Sr. Assistant Regional Counsel, U.S. Environmental Protection Agency, 841 Chestnut Building, Philadelphia, PA 19107, Phone: (215) 566–2487.

Dated: October 9, 1997.

Thomas Voltaggio,

Acting Regional Administrator, Region III.

[FR Doc. 97–27618 Filed 10–16–97; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

Notice of Public Information Collection(s) being Reviewed by the Federal Communications Commission

October 9, 1997.

SUMMARY: The Federal Communications Commission, as part of its continuing effort to reduce paperwork burden invites the general public and other Federal agencies to take this opportunity to comment on the following information collection(s), as required by the Paperwork Reduction Act of 1995, Public Law 104–13. An agency may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act (PRA) that does not display a valid control number. Comments are requested concerning (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimate; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology.

DATES: Written comments should be submitted on or before December 16, 1997. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all comments to Judy Boley, Federal Communications Commission, Room 234, 1919 M St., N.W., Washington, DC 20554 or via internet to jboley@fcc.gov.

FOR FURTHER INFORMATION CONTACT: For additional information or copies of the information collection(s), contact Judy Boley at 202–418–0214 or via internet at jboley@fcc.gov.

SUPPLEMENTARY INFORMATION:

OMB Approval No.: 3060–0182.

Title: Section 73.1620, Program Tests.

Form No.: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities; not-for-profit institutions.

Number of Respondents: 1,162.

Estimated Hour Per Response: 1–5 hours (1 hour for Section 73.1620(a)–(f); 5 hours for Section 73.1620(g)).

Frequency of Response: On occasion filing requirement.

Estimated Total Annual Burden: 1,226 hours.

Needs and Uses: Section 73.1620(a)(1) requires permittees of a nondirectional AM or FM station, or a nondirectional or directional TV station to notify the FCC upon beginning of program tests. An application for license must be filed within 10 days of this notification. Section 73.1620(a)(2) requires a permittee of an AM or FM station with a directional antenna to file a request for program test authority 10 days prior to date on which it desires to begin program tests. This is filed in conjunction with an application for license. Section 73.1620(f) requires licensees of UHF TV stations, assigned to the same allocated channel which a 1000 watt UHF translator station is authorized to use, to notify the licensee of the translator station at least 10 days prior to commencing or resuming operation and certify to the FCC that such advance notice has been given. Section 73.1620(g) requires permittees to report any deviation from their promises, if any, in their application for license to cover their construction permit (FCC Form 302) and on the first anniversary of their commencement of program tests. The notification in Section 73.1620(a) alerts the Commission that construction of a station has been completed and that the station is broadcasting program material. The notification in Section 73.1620(f) alerts the UHF translator station that the potential of interference exists. The report in Section 73.1620(g) stating deviations are necessary to eliminate possible abuses of the FCC's processes and to ensure that comparative promises relating to service to the public are not inflated.

OMB Approval No.: 3060–0187.

Title: Section 73.3594, Local Public Notice of Designation for Hearing.

Form No.: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities.

Number of Respondents: 14.

Estimated Hour Per Response: 3 hours (These hours include the contracting hour cost to the respondents and the respondents hour burden).

Frequency of Response: On occasion filing requirement.

Cost to Respondents: $24,000.

Estimated Total Annual Burden: 28 hours.

Needs and Uses: Section 73.3594 requires that applicants of any AM, FM or TV broadcast station designated for hearing must give notice of such designation. Section 73.3594(a) requires that this notice be given in a daily newspaper of general circulation published in the community in which the station is or will be located. This notice must be published twice a week for two consecutive weeks. Section 73.3594(b) requires applicants for modification, assignment, transfer or renewal of an operating broadcast station to give notice over the broadcast station in addition to publishing the notice in a daily newspaper. Section 73.3594(g) requires that applicants file a statement with the FCC setting forth information regarding the publication or broadcast. This notice gives interested parties an opportunity to respond.

OMB Approval No.: 3060–0190.

Title: Section 73.3544, Application to Obtain a Modified Station License.

Form No.: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities; not-for-profit institutions.

Number of Respondents: 363.

Estimated Hour Per Response: 2 hours (These hours include the contracting hour cost to the respondents and the respondents hour burden).

Frequency of Response: On occasion filing requirement.

Cost to Respondents: $47,375.

Estimated Total Annual Burden: 363 hours.

Needs and Uses: Section 73.3544 sets forth the filing procedures for broadcast licensees to obtain a modified station license when prior authority is not required to make changes to the station. Licensees are required to notify the FCC in writing when there is a change in the name of the licensee where there is no change in ownership or control. An informal application (written request) may be filed by licensees: (1) correcting the routing instructions and description of an AM station directional antenna system field monitoring point, when that point is not changed; (2) changing the type of AM station directional antenna monitor; (3) changing the location of the station main studio; or (4) changing the location of a remote control point of an AM or FM station.

TV or FM licensees changing the type of transmitting antenna or output power

of their transmitter must file the appropriate license application form (FCC Form 302–FM/302–TV, OMB Control Numbers 3060–0506/0029) with the FCC.

The data is used by FCC staff to ensure changes are in accordance with FCC rules and regulations and to issue a modified station license.

OMB Approval No.: 3060–0488.

Title: Section 73.30, Petition for Authorization of an Allotment in the 1605–1705 kHz Band.

Form No.: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities.

Number of Respondents: 1.

Estimated Hour Per Response: 2 hours (These hours include the contracting hour cost to the respondents and the respondents hour burden).

Frequency of Response: On occasion filing requirement.

Cost to Respondents: $200.

Estimated Total Annual Burden: 1 hour.

Needs and Uses: Section 73.30(a) requires any party interested in applying for an AM broadcast station to be operated on one of the ten channels in the 1605–1705 kHz band must first file a petition for the establishment of an allotment to its proposed community of service. Each petition must include the following information: (1) name of community for which allotment is sought; (2) station call letters; (3) frequency of its licensed operation; (4) whether operation with stereo is proposed. The data is used by FCC staff to determine whether applicant meets basic technical requirements to migrate to the expanded band.

OMB Approval No.: 3060–0489.

Title: Section 73.37, Applications for Broadcast Facilities, Showing Required.

Form No.: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities.

Number of Respondents: 285.

Estimated Hour Per Response: 6–16 hours (These hours include the contracting hour cost to the respondents and the respondents hour burden).

Frequency of Response: On occasion filing requirement.

Cost to Respondents: $428,125.

Estimated Total Annual Burden: 285 hours.

Needs and Uses: Section 73.37(d) requires an applicant for a new AM broadcast station, or for a major change in an authorized AM broadcast station, to make a satisfactory showing that objectionable interference will not result to an authorized AM station as a condition for its acceptance if new or modified nighttime operation by a Class B station is proposed.

Section 73.37(f) requires applicants seeking facilities modification that would result in spacings that fail to meet any of the separation requirements to include a showing that an adjustment has been made to the radiated signal which effectively results in a site-to-site radiation that is equivalent to the radiation of a station with standard Model 1 facilities.

The data is used by FCC staff to ensure that objectionable interference will not be caused to other authorized AM stations.

Federal Communications Commission.

William F. Caton,

Acting Secretary.

[FR Doc. 97–27516 Filed 10–16–97; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

Notice of Public Information Collection(s) Submitted to OMB for Review and Approval

October 10, 1997.

SUMMARY: The Federal Communications Commission, as part of its continuing effort to reduce paperwork burden invites the general public and other Federal agencies to take this opportunity to comment on the following information collection(s), as required by the Paperwork Reduction Act of 1995, Public Law 104–13. An agency may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act (PRA) that does not display a valid control number. Comments are requested concerning: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimate; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology.

DATES: Written comments should be submitted on or before November 17, 1997. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all comments to Judy Boley, Federal Communications Commission, Room 234, 1919 M St., N.W., Washington, DC 20554 or via internet to jboley@fcc.gov.

FOR FURTHER INFORMATION CONTACT: For additional information or copies of the information collection(s) contact Judy Boley at 202–418–0214 or via internet at jboley@fcc.gov.

SUPPLEMENTARY INFORMATION:

OMB Approval Number: 3060–XXXX.

Title: Long Form Application for Authorization in the Auctionable Services.

Form Number: FCC Form 601.

Type of Review: New collection.

Respondents: Individuals or households; business or other for-profit; not-for-profit institutions; state, local or tribal government.

Number of Respondents: 43,719.

Estimated Time Per Response: 2 hours.

Cost to Respondents: $23,224,619.

Total Annual Burden: 21,860 hours.

Needs and Uses: FCC Form 601 is a general application form for use by winners of FCC auctions and will be used as part of the Universal Licensing System. FCC Form 601 consists of a main form and a series of schedules containing technical information. Auction winning respondents will be required to submit FCC Form 601 electronically. There are no application fees, electronic filing fees or frequency coordination costs associated with filing this form.

OMB Approval Number: 3060–XXXX.

Title: Ownership Form.

Form Number: FCC Form 602.

Type of Review: New collection.

Respondents: Individuals or households; business or other for-profit; not-for-profit institutions; state, local or tribal government.

Number of Respondents: 10,000.

Estimated Time Per Response: 2 hours.

Cost to Respondents: $4,656,750.

Total Annual Burden: 5,000 hours.

Needs and Uses: FCC Form 602 will serve as a cover sheet to the ownership package and be used in addition to the extensive ownership collection information required by rule for each radio service. It will be used in conjunction with new applications, Transfers of Control, Assignments of Authorizations, and any other

ownership information updates required by rule. While the Commission is currently seeking approval only for the forementioned purpose, the Commission also anticipates continued use of FCC Form 602 for future auctions (market-based licensing) yet to be decided, as well as eventually expanding the uses of the form to replace other existing FCC forms/methods of collecting ownership information. FCC Form 602 is a new collection that eliminates lengthy ownership information being filed each time an applicant files. It will be a one-time annual filing of information for only the lone real party of interest that controls the license(s).

OMB Approval Number: 3060–XXXX.

Title: Application for Assignment of Authorization for Auctionable Services.

Form Number: FCC Form 603.

Type of Review: New collection.

Respondents: Individuals or households; business or other for-profit; not-for-profit institutions; state, local or tribal government.

Number of Respondents: 2,000.

Estimated Time Per Response: 4 hours.

Cost to Respondents: $1,952,450.

Total Annual Burden: 1,000 hours.

Needs and Uses: FCC Form 603 will be used to file for Assignment of Authorization. It will consist of a main form and a section to detail the call signs. While the Commission is currently seeking approval for use of the form for only auctionable service purposes, the Commission also anticipates continued use of FCC Form 603 for future auctions (market-based licensing) yet to be decided, as well as eventually expanding the uses of the form to replace other existing FCC forms/methods of collecting assignment of authorization information. This assignment form is a consolidated form and will be utilized as part of the Universal Licensing System (ULS) currently under development. The goal of producing a consolidated form is to create a form with a consistent ''look and feel'' that maximizes the collection of data and minimizes narrative responses, free-form attachment, and free-form letter requests. A consolidated assignment form will allow common fields, questions, and statements to reside in one place and allow the technical data specific to each service to be captured on its own form or schedule.

OMB Approval Number: 3060–XXXX.

Title: Application for Transfer of Control for Auctionable Services.

Form Number: FCC Form 604.

Type of Review: New collection.

Respondents: Individuals or households; business or other for-profit; not-for-profit institutions; state, local or tribal government.

Number of Respondents: 1,500.

Estimated Time Per Response: 3 hours.

Cost to Respondents: $1,164,338.

Total Annual Burden: 750 hours.

Needs and Uses: FCC Form 604 will be used to file for Transfer of Control for auctionable services. It will consist of a main form and a section to detail the transferred call signs. The form will only be filed by the licensee (transferor) on behalf of the transferor and the transferee. This transfer of control form is a consolidated form and will be utilized as part of the Universal Licensing System currently under development. Auctionable services respondents will be required to submit FCC Form 604 electronically. There are no application fees or electronic filing fees associated with filing of this form.

Federal Communications Commission.

LaVera F. Marshall,

Acting Secretary.

[FR Doc. 97–27634 Filed 10–16–97; 8:45 am]

BILLING CODE 6712–01–U

FEDERAL COMMUNICATIONS COMMISSION

[CC Docket No. 90–571; DA 97–2182]

Notice of Telecommunications Relay Services (TRS) Applications for State Certification Accepted

October 10, 1997.

Notice is hereby given that the states listed below have applied to the Commission for State Telecommunications Relay Service (TRS) Certification. Current state certifications expire July 25, 1998. Applications for certification, covering the five year period of July 26, 1998 to July 25, 2003, must demonstrate that the state TRS program complies with the Commission's rules for the provision of TRS, pursuant to Title IV of the Americans with Disabilities Act (ADA), 47 U.S.C. § 225. These rules are codified at 47 CFR 64.601–605.

Copies of applications for certification are available for public inspection at the Commission's Common Carrier Bureau, Network Services Division, Room 235, 2000 M Street, N.W., Washington, D.C., Monday through Thursday, 8:30 AM to 3:00 PM (closed 12:30 to 1:30 PM) and the FCC Reference Center, Room 239, 1919 M Street, N.W., Washington, D.C., daily, from 9 AM to 4:30 PM. Interested persons may file comments on or before December 12, 1997. Comments should reference the relevant state file number of the state application that is being commented upon. One original and five copies of all comments must be sent to William F. Caton, Acting Secretary, Federal Communications Commission, 1919 M Street, N.W., Washington, D.C. 20554. Two copies also should be sent to the Network Services Division, Common Carrier Bureau, 2000 M Street, N.W., Room 235, Washington, D.C. 20554.

A number of state TRS programs currently holding FCC certification have failed to apply for recertification. Applications received after October 1, 1997, for which no extension has been requested before October 1, 1997, must be accompanied by a petition explaining the circumstances of the late-filing and requesting acceptance of the late-filed application.

File No: TRS–97–38.

Applicant: Department of Health and Human Services, State of North Carolina.

File No: TRS–97–43.

Applicant: California Public Utiliities Commission, State of California.

File No. TRS–97–47.

Applicant: D.C. Public Service Commission, District of Columbia.

File No. TRS–97–48.

Applicant: Public Utility Commission of Texas, State of Texas.

For further information, contact Al McCloud, (202) 418–2499, amccloud@fcc.gov, or Andy Firth, (202) 418–2224 (TTY), afirth@fcc.gov, at the Network Services Division, Common Carrier Bureau, Federal Communications Commission.

Federal Communications Commission.

William F. Caton,

Acting Secretary.

[FR Doc. 97–27511 Filed 10–16–97; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL DEPOSIT INSURANCE CORPORATION

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Federal Deposit Insurance Corporation (FDIC).

ACTION: Notice and request for comment.

SUMMARY: The FDIC, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as

required by the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35). Currently, the FDIC is soliciting comments concerning an information collection titled ''Occasional Qualitative Surveys.''

DATES: Comments must be submitted on or before December 16, 1997.

ADDRESSES: Interested parties are invited to submit written comments to Tamara R. Manly, Management Analyst, (202) 898–7453, Office of the Executive Secretary, Federal Deposit Insurance Corporation, 550 17th Street NW., Washington, DC 20429. All comments should refer to ''Occasional Qualitative Surveys.'' Comments may be hand-delivered to Room F–4001B, 1776 F Street, NW., Washington, DC 20429, on business days between 8:30 a.m. and 5:00 p.m. [FAX number (202) 898–3838; Internet address: comments@fdic.gov].

A copy of the comments may also be submitted to the OMB desk officer for the FDIC: Alexander Hunt, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 3208, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Tamara R. Manly, at the address identified above.

SUPPLEMENTARY INFORMATION: Proposal to renew the following currently approved collection of information:

Title: Occasional Qualitative Surveys.

OMB Number: New collection.

Frequency of Response: Occasional.

Affected Public: Business institutions and other federal and government agencies.

Estimated Number of Respondents: 5,000.

Estimated Time per Response: 1 hour.

Estimated Total Annual Burden: 5,000 hours.

General Description of Collection: The collection involves the occasional use of qualitative surveys to gather anecdotal information about regulatory burden, problems or successes in the bank supervisory process (including both safety-and-soundness and consumer-related exams), and similar concerns.

Request for Comment

Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the FDIC's functions, including whether the information has practical utility; (b) the accuracy of the estimates of the burden of the information collection, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

At the end of the comment period, the comments and recommendations received will be analyzed to determine the extent to which the collection should be modified prior to submission to OMB for review and approval. Comments submitted in response to this notice also will be summarized or included in the FDIC's requests to OMB for renewal of this collection. All comments will become a matter of public record.

Dated at Washington, DC, this 14th day of October, 1997.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

[FR Doc. 97–27612 Filed 10–16–97; 8:45 am]

BILLING CODE 6714–01–M

FEDERAL DEPOSIT INSURANCE CORPORATION

Community Reinvestment Act; Rescission of Statement of Policy

AGENCY: Federal Deposit Insurance Corporation (FDIC).

ACTION: Rescission of statement of policy.

SUMMARY: As part of the FDIC's systematic review of its regulations and written policies under section 303(a) of the Riegle Community Development and Regulatory Improvement Act of 1994 (CDRIA), the FDIC is rescinding its Statement of Policy on the ''Community Reinvestment Act.'' The statement of policy has been rendered obsolete by the amendment of part 345 (Community Reinvestment) of the FDIC's regulations, and thus is being rescinded. This action furthers the goals of section 303(a) of CDRIA by removing inconsistencies and outmoded and duplicative requirements from the FDIC's supervisory policies.

DATES: The statement of policy is rescinded effective October 17, 1997.

FOR FURTHER INFORMATION CONTACT: Louise N. Kotoshirodo, Review Examiner, Division of Compliance and Consumer Affairs (202–942–3599), or Ann Hume Loikow, Counsel, Legal Division (202–898–3796), FDIC, 550 17th Street, N.W., Washington, D.C. 20429.

SUPPLEMENTARY INFORMATION: The FDIC is conducting a systematic review of its regulations and policy statements pursuant to section 303(a) of the Riegle Community Development and Regulatory Improvement Act of 1994 (CDRIA) (12 U.S.C. 4803(a)), which requires the FDIC, the Office of the Comptroller of the Currency, the Office of Thrift Supervision, and the Board of Governors of the Federal Reserve System (agencies) to streamline and modify their regulations and written policies in order to improve efficiency, reduce unnecessary costs, and eliminate unwarranted constraints on credit availability. Section 303(a) also requires the agencies to remove inconsistencies and outmoded and duplicative requirements.

The FDIC adopted jointly with the agencies a new part 345 to the FDIC's rules and regulations, entitled ''Community Reinvestment,'' to implement the Community Reinvestment Act of 1977 (CRA), which was published in the **Federal Register** on October 12, 1978 (43 FR 47144). On March 31, 1980, the FDIC Board of Directors adopted a Statement of Policy on the Community Reinvestment Act (Statement of Policy) which discussed the act and regulations, how FDIC examiners would assess a bank's record of meeting community credit needs, and how the FDIC would take such assessment into account when evaluating various types of applications for deposit facilities.

On May 4, 1995, the FDIC published jointly with the agencies, significant amendments to part 345 of the FDIC's rules and regulations (60 FR 22156). Subsequent technical amendments were made to part 345 and published in the **Federal Register** on December 20, 1995 (60 FR 66048) and May 10, 1996 (61 FR 21362), respectively. Part 345 of the FDIC's rules and regulations, as amended, reduces unnecessary regulatory burden and replaces the 12 assessment factors contained in the 1979 rule and Statement of Policy with a more performance-based evaluation process to assess a bank's record in meeting the credit needs of its community, including low- and moderate-income neighborhoods. The new regulation was phased in over a two-year period beginning July 1, 1995. On July 1, 1997, all remaining portions of the rule became effective and all insured state nonmember banks are now evaluated under the new CRA performance tests.

As part of the Corporation's regulatory review project required by section 303(a) of CDRIA, the Board has reviewed the Statement of Policy and determined that the supervisory guidance contained in it has been rendered obsolete by the amendment of part 345 and should be rescinded. Furthermore, the Board concludes that rescission of this Statement of Policy

would further the goal of section 303(a) of CDRIA of removing inconsistencies and outmoded and duplicative requirements.

Rescission of this Statement of Policy does not reflect any substantive change in the FDIC's supervisory attitude toward insured state nonmember banks' compliance with the Community Reinvestment Act and part 345.

For the foregoing reasons, the Statement of Policy is hereby rescinded.

By order of the Board of Directors.

Dated at Washington, D.C. this 6th day of October, 1997.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

[FR Doc. 97–27518 Filed 10–16–97; 8:45 am]

BILLING CODE 6714–01–P

FEDERAL DEPOSIT INSURANCE CORPORATION

Sunshine Act Meeting

Pursuant to the provisions of the ''Government in the Sunshine Act'' (5 U.S.C. 552b), notice is hereby given that at 10:03 a.m. on Tuesday, October 14, 1997, the Board of Directors of the Federal Deposit Insurance Corporation met in closed session to consider matters relating to the Corporation's corporate and supervisory activities.

In calling the meeting, the Board determined, on motion of John F. Downey, acting in the place and stead of Director Nichols P. Retsinas (Director, Office of Thrift Supervision), seconded by Julie L. Williams, acting in the place and stead of Eugene A. Ludwig (Comptroller of the Currency), concurred in by Director Joseph H. Neely (Appointive), and Acting Chairman Andrew C. Hove, Jr., that Corporation business required its consideration of the matters on less than seven days' notice to the public; that no earlier notice of the meeting was practicable; that the public interest did not require consideration of the matters in a meeting open to public observation; and that the matters could be considered in a closed meeting by authority of subsections (c)(2), (c)(4), (c)(6), (c)(8), (c)(9)(A)(ii), (c)(9)(B) and (c)(10) of the ''Government in the Sunshine Act'' (5 U.S.C. 552b(c)(2), (c)(4), (c)(6), (c)(8), (c)(9)(A)(ii), (c)(9)(B), and (c)(10)).

The meeting was held in the Board Room of the FDIC Building located at 550—17th Street, N.W., Washington, D.C.

Dated: October 14, 1997.

Federal Deposit Insurance Corporation.

James D. LaPierre,

Deputy Executive Secretary.

[FR Doc. 97–27690 Filed 10–15–97; 10:14 am]

BILLING CODE 6714–01–M

FEDERAL MARITIME COMMISSION

Notice of Agreement(s) Filed

The Commission hereby gives notice of the filing of the following agreement(s) under the Shipping Act of 1984.

Interested parties can review or obtain copies of agreements at the Washington, DC offices of the Commission, 800 North Capitol Street, N.W., Room 962. Interested parties may submit comments on an agreement to the Secretary, Federal Maritime Commission, Washington, DC 20573, within 10 days of the date this notice appears in the **Federal Register**.

Agreement No.: 224–201036.

Title: Port of New Orleans/Maritrend, Inc. Lease Agreement.

Parties:

The Board of Commissioners of the Port of New Orleans (''Port'')

Maritrend, Inc. (''Maritrend'')

Synopsis: The proposed Agreement authorities the Port to lease to Maritrend 9.33 acres, and improvements thereon, at the Port's Alabo Street facilities for a period of one year, with the option to extend the lease for two additional renewal periods of one year each.

Dated: October 10, 1997.

By Order of the Federal Maritime Commission.

Ronald D. Murphy,

Assistant Secretary.

[FR Doc. 97–27533 Filed 10–16–97; 8:45 am]

BILLING CODE 6730–01–M

FEDERAL MARITIME COMMISSION

Ocean Freight Forwarder License Applicants

Notice is hereby given that the following applicants have file with the Federal Maritime Commission applications for licenses as ocean freight forwarders pursuant to section 19 of the Shipping Act of 1984 (46 U.S.C. app. 1718 and 46 CFR 510).

Persons knowing of any reason why any of the following applicants should not receive a license are requested to contact the Office of Freight Forwarders, Federal Maritime Commission, Washington, DC 20573.

Esprit International Shipping Combined Transport, Inc., 7940 E. Garvey Avenue, Suite 203, Rosemead, CA 91770, *Officers:* Amy Choi, President, Tracy Cheuk-See Chan, Vice President

Bestway Shipping, Inc., 269 E. Redondo Beach Blvd., Gardena, CA 90248, *Officer:* Harry Hyungsuk Choi, President

III Star Freight Services, Inc., 140 Eastern Avenue, Chelsea, MA 02150, *Officers:* Mikhail Kravetskil, President, Joseph A. Scali, Treasurer

Asian Pacific Logistics, 23202 Audrey Avenue, Torrance, CA 90505, Paul Yoon, Sole Proprietor

Unlimited Logistics, 2395 Giltner Road, Smithfield, KY 40068, Martha A. Works

Pacific Shipping Company, 1011 Klickitat Way, Suite 203, Seattle, WA 98134, *Officers:* Kim Knise, President, James G. Rosselot, Vice President

Maromar International Freight Forwarders Inc., 8262 N.W. 14th Street, Miami, FL 33126, *Officers:* Maricel Barth, President, Marta Barth, Operations Director

Guardian Moving and Storage Co., Inc. d/b/a Guardian International Forwarders, 1901 Light Street, Baltimore, MD 21202, *Officers:* Eugene W. Smoot, President, Mario S. Smoot, Vice President

Global Marine Services, Inc., 2085 Talleyrand Avenue, Building ''A'', P.O. Box 2239, Jacksonville, FL 32206, *Officers:* Carlton H. Spence, Director, Jeffrey C. Spence, Director/ President.

Dated: October 10, 1997.

Ronald D. Murphy,

Assistant Secretary.

[FR Doc. 97–27534 Filed 10–16–97; 8:45 am]

BILLING CODE 6730–01–M

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of Banks or Bank Holding Companies

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices

of the Board of Governors. Comments must be received not later than October 30, 1997.

A. Federal Reserve Bank of Cleveland (Jeffery Hirsch, Banking Supervisor) 1455 East Sixth Street, Cleveland, Ohio 44101-2566:

1. Billy Miller Smith, Hindman, Kentucky; Marcia Lawrence, Lexington, Kentucky; Valerie Smith Bartley, Pikeville, Kentucky; Tracey Smith Weinberg, Hindman, Kentucky; Carew Smith Barley, Pikeville, Kentucky; Benjamin Lee Smith, Archbold, Ohio; Stuart Granby Smith, Leburn, Kentucky; Dirk Smith Trust, Hindman, Kentucky; William Dirk Smith, Hindman, Kentucky; William Samuel Smith, Archbold, Ohio; National City Bank, Trustee for U/W Philip Lawrence, Cleveland, Ohio, collectively referred to as the Smith Family; to acquire voting shares of Hindman Bancshares, Inc., Hindman, Kentucky, and thereby indirectly Hindman Bank, Hindman, Kentucky.

B. Federal Reserve Bank of San Francisco (Pat Marshall, Manager of Analytical Support, Consumer Regulation Group) 101 Market Street, San Francisco, California 94105-1579:

1. Wendell A. Jacobson, Fountain Green, Utah; to acquire additional voting shares of Bank of Ephraim, Ephraim, Utah.

Board of Governors of the Federal Reserve System, October 10, 1997.

William W. Wiles,

Secretary of the Board.

[FR Doc. 97–27510 Filed 10-16-97; 8:45 am]

BILLING CODE 6210-01-F

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies; Correction

This notice corrects a notice (FR Doc. 97-26546) published on page 52339 of the issue for Tuesday, October 7, 1997.

Under the Federal Reserve Bank of Dallas heading, the entry for Amador Merger Corporation, Las Cruces, New Mexico, is revised to read as follows:

A. Federal Reserve Bank of Dallas (Genie D. Short, Vice President) 2200 North Pearl Street, Dallas, Texas 75201-2272:

1. Amador Merger Corporation, Las Cruces, New Mexico; to become a bank holding company by acquiring 100 percent of the Amador Bancshares, Inc., Las Cruces, New Mexico, and thereby indirectly acquire Citizens Bank of Las Cruces, Las Cruces, New Mexico.

Comments on this application must be received by October 31, 1997.

Board of Governors of the Federal Reserve System, October 10, 1997.

William W. Wiles,

Secretary of the Board.

[FR Doc. 97–27508 Filed 10–16–97; 8:45 am]

BILLING CODE 6210-01-F

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR Part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The application also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act. Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than November 10, 1997.

A. Federal Reserve Bank of Chicago (Philip Jackson, Applications Officer) 230 South LaSalle Street, Chicago, Illinois 60690-1413:

1. Fidelity Ban Corporation, Independence, Iowa; to acquire 100 percent of the voting shares of Benton County Savings Bank, Norway, Iowa.

Board of Governors of the Federal Reserve System, October 10, 1997.

William W. Wiles,

Secretary of the Board.

[FR Doc. 97–27509 Filed 10–16–97; 8:45 am]

BILLING CODE 6210-01-F

FEDERAL RESERVE SYSTEM

Sunshine Act Meeting

AGENCY HOLDING THE MEETING: Board of Governors of the Federal Reserve System.

TIME AND DATE: 10:00 a.m., Wednesday, October 22, 1997.

PLACE: Marriner S. Eccles Federal Reserve Board Building, 20th and C Streets, NW., Washington, DC 20551.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.

2. Any items carried forward from a previously announced meeting.

CONTACT PERSON FOR MORE INFORMATION: Mr. Joseph R. Coyne, Assistant to the Board; (202) 452–3204. You may call (202) 452–3207, beginning at approximately 5 p.m. two business days before this meeting, for a recorded announcement of bank and bank holding company applications scheduled for the meeting.

Dated: October 15, 1997.

Jennifer J. Johnson,

Deputy Secretary of the Board.

[FR Doc. 97–27702 Filed 10–15–97; 11:34 am]

BILLING CODE 6210–01–P

FEDERAL TRADE COMMISSION

Submission for OMB Review; Comment Request

AGENCY: Federal Trade Commission.

ACTION: Submission for OMB review; comment request.

SUMMARY: The FTC has submitted information collection requirements associated with the Alternative Fuel Rule, 16 CFR part 309, to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520). On July 25, 1997, the FTC solicited comments from the public concerning these information collection requirements, and provided the information specified in 5 CFR 1320.5(a)(1)(iv). 62 FR 40089. No comments were received. The current OMB clearance for these requirements expires on November 30, 1997. The FTC has requested that OMB extend the PRA clearance through November 30, 2000.

DATES: Comments must be filed by November 17, 1997.

ADDRESSES: Send comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 3228, Washington, D.C. 20530, ATTN: Edward Clarke, Desk Officer for the Federal Trade Commission. Comments may also be sent to Elaine W. Crockett, Attorney, Office of the General Counsel, Room 598, 6th St. and Pennsylvania Ave., N.W. 20580, telephone: (202) 326–2453; fax: (202) 326–2477; e-mail ecrockettftc.gov.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the proposed extensions of the information requirements should be addressed to Elaine W. Crockett at the address listed above.

SUPPLEMENTARY INFORMATION: *Title*: Alternative Fuel Rule, 16 CFR part 309—(OMB Control Number 3084–0094)—Extension. On May 9, 1995, the Commission issued the Alternative Fuel Rule, which requires disclosure of specific information on labels posted on fuel dispensers for non-liquid alternative fuels, and on labels on alternative fueled vehicles (AFVs). To ensure the accuracy of the labeling disclosures, the Rule also requires that sellers maintain records substantiating the product-specific disclosures that they include on these labels. The labeling requirements provide consumers with reliable and comparable information about the fuel ratings of similar types of fuel and alternative fueled vehicles. The primary purpose of the recordkeeping requirements is to preserve evidence of compliance with the Rule.

Burden statement: The Rule, which primarily establishes fuel rating determination, certification, labeling, and recordkeeping requirements, imposes burden on the alternative vehicle fuel industry and the alternative fuel vehicle manufacturing industry. When the Rule was issued in 1995, the FTC found that the non-liquid alternative vehicle fuel industry consisted of approximately 1,600 members, of which approximately 1,300 import, produce, refine, distribute or retail compressed natural gas to the public for use in alternative fueled vehicles. The FTC also estimated that approximately 50 industry members manufacture or distribute electric vehicle fuel dispensing systems and that no more than 250 companies retail electricity to the public through electric vehicle fuel dispensing systems. As to the alternative fueled vehicle industry, the FTC found that approximately 58 companies manufactured such vehicles and were subject to labeling and recordkeeping requirements. Staff at the Department of Energy inform us that the current numbers for both industries are approximately the same as they were in 1995.

1995 Non-Liquid Alternative Fuel Burden Hour Estimates

Determination and Certification: In 1995, staff estimated that the Rule's fuel rating determination requirements and the Rule's fuel rating certification requirements would affect approximately 350 industry members which produce natural gas and distribute and manufacture electric vehicle fuel dispensing systems. *Labeling:* Staff also estimated that labeling requirements would affect approximately nine of every ten industry members (or 1,400 members), but the number of affected members would decrease in subsequent years because labels may remain effective for several years. *Recordkeeping:* Staff estimated that all 1,600 industry members would be subject to the Rule's recordkeeping requirements.

1995 Alternative Fueled Vehicle Burden Hour Estimates

Labeling: Producing: In 1995, staff estimated that there were approximately 350,000 AFVs, consisting of 36 models. Staff rounded the number of models to 40 to allow for the introduction of new AFV models into the marketplace. Further, staff estimated 2.5 hours as the average time required to produce labels for each of the 40 models. *Labeling: Posting:* Staff estimated the average time to comply with the posting requirements to be 2 minutes for each of the 350,000 vehicles. *Recordkeeping:* Staff estimated that all 58 manufacturers would require 30 minutes to comply with the Rule's recordkeeping requirements. Accordingly, in 1995, burden hours were calculated as follows:

Fuel Rating Determination: 2 hours x 350 industry members = 700 burden hours.

Fuel Rating Certification: 24 hours x 350 industry members = 8,400 burden hours.

Labeling: 1 hour x 1,400 industry members = 1,400 burden hours.

Recordkeeping associated with fuel rating determination and certification: 6 minutes x 1,600 industry members = 160 hours.

AFV labeling: producing: 2.5 hours x 40 models = 100 burden hours; posting: 2 minutes x 350,000 AFVs = 11,667 burden hours; recordkeeping: 30 minutes x 58 industry members = 29 burden hours.

Total 1995 burden hours: 22,500 (rounded).

1997 Burden Hour Estimates

In 1997, all of the requirements related to the processes involved in fuel rating determination, certification, labeling, and recordkeeping remain the same, We have, however, reduced the 1995 total burden estimate of 22,500 hours because, as stated in the original application for PRA clearance, it is now and always has been, common practice for industry members to determine and monitor fuel ratings in the normal course of their business activities. This is because industry members must know and determine the fuel ratings of their products in order to monitor quality and to decide how to market them. ''Burden'' for OMB purposes is defined to exclude effort that would be expended regardless of any regulatory requirement 5 CFR 1320.2(b)(2).

One-time letters of certification or the use of permanent marks or labels on electric vehicle fuel dispensing systems may be used once and thereafter remain in effect for several years. Also, the specifications for labels were designed to produce a label that would withstand the elements for several years. Nonetheless, there is still some burden associated with producing, distributing, posting, and maintaining new labels. There also will be some burden associated with new or revised certification of fuel ratings. The burden on vehicle manufacturers will be less because label production will be needed for only a few models and because only newly-manufactured vehicles will require label posting. Accordingly, we have calculated the revised burden hour estimates as follows:

(Fuel Rating Determination numbers are no longer applicable because these numbers are no longer associated with start-up costs and are determined during the ordinary course of business).

Fueld Rating Certification: 1 hour x 350 industry members = 350 burden hours.

Labeling: 1 hour x 280 industry members = 280 burden hours. (This calculation assumes that only 20% of 1,400 industry members will be affected because it is unnecessary to replace labels each year.)

Recordkeeping associated with fuel rating determination and certification: 6 minutes x 1,600 industry members = 160 burden hours.

AFV labeling: producing: 2.5 hours x 5 new models per year = 12.5 burden hours; posting: 2 minutes x 20,000 new AFVs per year = 667 burden hours. (The number of new AFVs per year was determined after discussions with staff at the Department of Energy.);

recordkeeping: 30 minutes x 58 industry members = 29 burden hours.

Total 1997 burden hours: approximately 1,500 (rounded).

To re-emphasize, the FTC is not amending, nor is it in the process of amending, the Alternative Fuel Rule. The burden hours associated with the Rule have been recalculated because, as originally anticipated when the Rule was promulgated in 1995, many of the information collection requirements collection requirements and the originally-estimated hours were associated with one-time start up tasks of implementing standard systems and processes. In addition, the FTC has reduced the estimated burden hours because the industry complies with many of these requirements in the ordinary course of business and, as stated above, the definition of ''burden'' excludes effort that would be expended regardless of any regulatory requirement. 5 CFR 1320.2(b)(2).

Debra A. Valentine,

General Counsel.

[FR Doc. 97–27620 Filed 10–16–97; 8:45 am]

BILLING CODE 6750–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Hospital Infection Control Practices Advisory Committee Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following meeting.

Name: Hospital Infection Control Practices Advisory Committee (HICPAC).

Times and Dates: 8:30 a.m.–5 p.m., November 17, 1997 and 8:30 a.m.–1 p.m., November 18, 1997.

Place: Centers for Disease Control and Prevention, Building 16, Room 1107/1107A, 1600 Clifton Road, NE, Atlanta, Georgia 30333.

Status: Open to the public, limited only by the space available. In addition to the Committee, the room will accommodate approximately 25 guests.

Purpose: The Committee is charged with providing advice and guidance to the Secretary, the Assistant Secretary for Health, the Director, CDC, and the Director, National Center for Infectious Diseases (NCID), regarding (1) the practice of hospital infection control; (2) strategies for surveillance, prevention, and control of nosocomial infections in U.S. hospitals; and (3) updating guidelines and other policy statements regarding prevention of nosocomial infections.

Matters to be Discussed: Agenda items will include an overview of Strategic Direction of HICPAC; a review of the public response to the Draft Guideline for Infection Control in Hospital Personnel; a review of the second draft of the Guideline for Prevention of Surgical Site Infections; and a review of CDC activities of interest to the Committee.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Michele L. Pearson, M.D., Medical Epidemiologist, Investigation and Prevention Branch, Hospital Infections Program, NCID, CDC, 1600 Clifton Road, NE, M/S E–69, Atlanta, Georgia 30333, telephone 404/639–6413.

Dated: October 8, 1997.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 97–27568 Filed 10–16–97; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Notice of Meeting

The National Center for Environmental Health (NCEH) of the Centers for Disease Control and Prevention (CDC) announces the following meetings.

Name: Workshop on Screening and Tracking Systems for Early Hearing Detection and Intervention (EHDI).

Times and Dates: 8 a.m.–5 p.m., October 22, 1997; 8:30 a.m.–1 p.m., October 23, 1997; 8 a.m.–5 p.m., December 11, 1997; 8:30 a.m.–1 p.m., December 12, 1997.

Place: Sheraton Colony Square Hotel, 188 14th Street, NE, Atlanta, Georgia 30346. Telephone 404/892–6000 or 800/422–7865.

Status: Meetings will be open for participation by anyone with an interest in EHDI data systems.

Purpose: To explore the feasibility of an integrated data management and tracking system for hearing impairment and other childhood disabilities. Participants will review the evidence and issues related to a public health decision to screen all infants and will discuss ways in which early hearing detection and intervention could be implemented.

Matters to be Discussed: Invited Speakers will present issues and describe existing systems. Topics to be discussed during the meetings include (1) evidence related to the screening of all infants for hearing impairment; (2) current developments in tracking systems for childhood disabilities; (3) issues to be considered; (4) whether a centralized tracking system developed for EHDI can contribute to an integrated data management system of childhood disabilities.

CONTACT PERSON FOR MORE INFORMATION: June Holstrum, Ph.D., Division of Birth Defects and Developmental Disabilities, CDC, NCEH, 4770 Buford Highway, NE, M/S F–15, Atlanta, Georgia 30341, e-mail: ehdi@cdc.gov, telephone 770/488–7401, fax 770/488–7361.

Dated: October 8, 1997.

Carolyn J. Russell,

Director, Management Analysis and Services Office Centers for Disease Control and Prevention (CDC).

[FR Doc. 97–27571 Filed 10–16–97; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[Program Announcement No. 93612–972]

Administration for Native Americans; Notice

Availability of Financial Assistance for the Mitigation of Environmental Impacts to Indian Lands Due to Department of Defense Activities

On September 5, 1996, in Vol. 61, No. 173 of the **Federal Register**, pages 46994 to 46999, the Administration for Native Americans announced the ''Availability of Finance Assistance for the Mitigation of Environmental Impacts to Indian Lands due to Department of Defense Activities''. For purposes of this program announcement, Indian land is defined as all lands used by American Indian tribes and Alaska Native villages.

Two deadline dates for submission of applications were published in this announcement: November 8, 1996 and November 7, 1997. This notice serves as a reminder for the November 7, 1997 deadline for submission of applications.

Dated: October 10, 1997.

Gary N. Kimble,

Commissioner, Administration for Native Americans.

[FR Doc. 97–27619 Filed 10–16–97; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 95N–0070]

Hedviga Herman; Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing an order under the Federal Food, Drug, and Cosmetic Act (the act) permanently debarring Ms. Hedviga Herman, 1326 42d St., Brooklyn, NY 11219, from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on a finding that Ms. Herman was convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the act. Ms. Herman has failed to request a hearing and, therefore, has waived her opportunity for a hearing concerning this action.

EFFECTIVE DATE: October 17, 1997.

ADDRESSES: Application for termination of debarment to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Christine F. Rogers, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION:

I. Background

On September 23, 1994, the United States District Court for the District of Maryland entered judgment against Ms. Hedviga Herman for, among other counts: (1) One count of introducing adulterated drugs into interstate commerce, a Federal felony offense under 21 U.S.C. 331(a) and 333(a)(2); (2) one count of introducing unapproved new drugs into interstate commerce, a Federal felony offense under 21 U.S.C. 331(d) and 333(a)(2); and (3) one count of obstruction of an agency proceeding, a Federal felony offense under 18 U.S.C. 1505.

As a result of these convictions, FDA served Ms. Herman by certified mail on February 20, 1996, a notice proposing to permanently debar her from providing services in any capacity to a person that has an approved or pending drug product application, and offered her an opportunity for a hearing on the proposal. The proposal was based on a finding, under section 306(a)(2)(B) of the act (21 U.S.C. 335a(a)(2)(B)), that she was convicted of a felony under Federal law for conduct relating to the regulation of a drug product. Ms. Herman was provided 30 days to file objections and request a hearing. Ms. Herman did not request a hearing. Her failure to request a hearing constitutes a waiver of her opportunity for a hearing and a waiver of any contentions concerning her debarment.

II. Findings and Order

Therefore, the Director, Center for Drug Evaluation and Research, under section 306(a)(2)(B) of the act, and under authority delegated to her (21 CFR 5.99), finds that Ms. Hedviga Herman has been convicted of a felony under Federal law for conduct relating to the regulation of a drug product.

As a result of the foregoing finding, Ms. Hedviga Herman is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application under section 505, 507, 512, or 802 of the act (21 U.S.C. 355, 357, 360b, or 382), or under section 351 of the Public Health Service Act (42 U.S.C. 262), effective October 17, 1997 (sections 306(c)(1)(B) and (c)(2)(A)(ii) and 201(dd) of the act (21 U.S.C. 321(dd))). Any person with an approved or pending drug product application who knowingly uses the services of Ms. Herman, in any capacity, during her period of debarment, will be subject to civil money penalties (section 307(a)(6) of the act (21 U.S.C. 335b(a)(6))). If Ms. Herman, during her period of debarment, provides services in any capacity to a person with an approved or pending drug product application, she will be subject to civil money penalties (section 307(a)(7) of the act). In addition, FDA will not accept or review any abbreviated new drug applications submitted by or with the assistance of Ms. Herman during her period of debarment.

Any application by Ms. Herman for termination of debarment under section 306(d)(4) of the act should be identified with Docket No. 95N–0070 and sent to the Dockets Management Branch (address above). All such submissions are to be filed in four copies. The public availability of information in these submissions is governed by 21 CFR 10.20(j). Publicly available submissions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 1, 1997.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 97–27586 Filed 10–16–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97F–0421]

Yoshitomi Fine Chemicals, Ltd.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Yoshitomi Fine Chemicals, Ltd., has filed a petition proposing that the food additive regulations be amended to provide for the safe use of Di-tert-butylcresyl phosphonite condensation product with biphenyl for use as an antioxidant and/or stabilizer for olefin polymers intended for use in contact with food.

FOR FURTHER INFORMATION CONTACT: Hortense S. Macon, Center for Food Safety and Applied Nutrition (HFS–205), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3086.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 7B4557) has been filed by Yoshitomi Fine Chemicals, Ltd., 6–9 Hiranomachi 2-chome, Chuo-ku, Osaka 541, Japan. The petition proposes to amend the food additive regulations in § 178.2010 *Antioxidants and/or stabilizers for polymers* (21 CFR 178.2010) to provide for the safe use of Di-tert-butylcresyl phosphonite condensation product with biphenyl,produced by the condensation of 2,4-di-tert-butylcresol with the Friedel-Crafts addition product of phosphorous trichloride and biphenyl,for use as an antioxidant and/or stabilizer for olefin polymers intended for use in contact with food.

The agency has determined under 21 CFR 25.32(i) that this action is of the type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: September 23, 1997.

Alan M. Rulis,

Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 97–27532 Filed 10–16–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Anti-Infective Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Anti-Infective Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA regulatory issues.

Date and Time: The meeting will be held on November 19 and 20, 1997, 8 a.m. to 5:30 p.m.; and November 21, 1997, 8 a.m. to 2 p.m.

Location: Holiday Inn, Versailles Ballrooms III and IV, 8120 Wisconsin Ave., Bethesda, MD.

Contact Person: Ermona B. McGoodwin or Danyiel A. D'Antonio, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–5455, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12530. Please call the Information Line for up-to-date information on this meeting.

Agenda: On November 19, 1997, the committee will discuss issues relating to the development of fluoroquinolones for use in pediatric patients. On the morning of November 20, 1997, the committee will discuss new drug application (NDA) 50–585/S046, ceftriaxone sodium (Rocephin® sterile vials, Roche Laboratories) for single dose intramuscular treatment of acute otitis media. On the afternoon of November 20, 1997, the committee will discuss NDA 20–799, ofloxacin otic (Floxin®, Daiichi Pharmaceuticals) for treatment of otitis externa, chronic suppurative otitis media with perforated tympanic membrane, and acute otitis media in pediatric patients with tympanostomy tubes. On November 21, 1997, the committee will discuss NDA 50–753, tobramycin solution for inhalation (TOBI®, PathoGenesis Corp.) for the management of cystic fibrosis patients.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by November 12, 1997. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. on November 19 and 20, and between approximately 11 a.m. and 12 m. on November 21. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before November 12, 1997, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: October 9, 1997.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 97–27530 Filed 10–16–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Peripheral and Central Nervous System Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Peripheral and Central Nervous System Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on regulatory issues.

Date and Time: The meeting will be held on November 18 and 19, 1997, 8:30 a.m. to 5 p.m.

Location: Quality Hotel, Maryland Ballroom, 8727 Colesville Rd., Silver Spring, MD.

Contact Person: Ermona McGoodwin or Danyiel D'Antonio, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–5455, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12543. Please call the Information Line for up-to-date information on this meeting.

Agenda: On November 18, 1997, the Committee will discuss the evidence of safety and effectiveness in new drug application (NDA) 20–861, Prosynap (lubeluzole injection, Janssen Research Foundation) for the treatment of acute ischemic stroke in adults. On November 19, 1997, the Committee will discuss the evidence of safety and effectiveness in NDA 20–764, Lamictal CD Chewable Dispersible Tablets (lamotrigine, Glaxo Wellcome) for the treatment of the generalized seizures of Lennox-Gastaut syndrome in pediatric and adult patients.

Procedure: Interested persons may present data, information, or views, orally, or in writing, on issues pending before the Committee. Written submissions may be made to the contact person by November 12, 1997. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. on November 18, 1997, and between 9 a.m. and 10 a.m. on November 19, 1997. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before November 12, 1997, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app.2).

Dated: October 9, 1997.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 97–27529 Filed 10–16–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Advisory Committee for Pharmaceutical Science; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Advisory Committee for Pharmaceutical Science.

General Function of the Committee: To provide advice and recommendations to the agency on FDA regulatory issues.

Date and Time: The meeting will be held on December 11 and 12, 1997, 8:30 a.m. to 5:30 p.m.

Location: Quality Hotel, Maryland Room, 8727 Colesville Rd., Silver Spring, MD.

Contact Person: Kimberly Littleton Topper, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–5455, (FedEx—Chapman Bldg., 801 Thompson Ave., rm. 200, Rockville, MD 20852), or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12539. Please call the Information Line for up-to-date information on this meeting.

Agenda: On December 11, 1997, the committee will discuss the Biopharmaceutics Classification System, topicals-dermatological drug products, and Narrow Therapeutic Index Drugs and relevance to product quality testing. On December 12, 1997, the committee will discuss the drug-drug interaction studies, and bioequivalence studies that fail to meet established confidence intervals.

Procedure: Interested persons may present data, information, or views, orally, or in writing, on issues pending before the committee. Written submissions may be made to the contact person by December 1, 1997. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. on December 11, 1997, and between approximately 1:30 p.m. and 2 p.m. on December 12, 1997. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before December 1, 1997, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: October 9, 1997.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 97–27531 Filed 10–16–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Veterinary Medicine Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Veterinary Medicine Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA regulatory issues.

Date and Time: The meeting will be held on November 12 and 13, 1997, 8:30 a.m. to 4:30 p.m.

Location: Holiday Inn, Goshen Room, Two Montgomery Village Ave., Gaithersburg, MD.

Contact Person: Jacquelyn L. Pace, Center for Veterinary Medicine (HFV–200), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–5920, FAX 301–594–4512, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12546. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss veterinary medical issues related to the quality standards for the manufacture of animal drugs, such as current good manufacturing practices. Requests for the tentative questions for committee discussion may be addressed to the contact person (address above).

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by November 5, 1997. Oral presentations from the public will be scheduled between approximately 1 p.m. and 3 p.m. on November 12, 1997. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before November 5, 1997, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: October 9, 1997.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 97–27528 Filed 10–16–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4235–N–25]

Federal Property Suitable as Facilities to Assist the Homeless

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice.

SUMMARY: This Notice identifies unutilized, underutilized, excess, and surplus Federal property reviewed by HUD for suitability for possible use to assist the homeless.

FOR FURTHER INFORMATION CONTACT: Mark Johnston, room 7256, Department of Housing and Urban Development, 451 Seventh Street SW, Washington, DC 20410; telephone (202) 708–1226; TDD number for the hearing- and speech-impaired (202) 708–2565 (these telephone numbers are not toll-free), or call the toll-free Title V information line at 1–800–927–7588.

SUPPLEMENTARY INFORMATION: In accordance with 24 CFR part 581 and section 501 of the Steward B. McKinney Homeless Assistance Act (42 U.S.C. 11411), as amended, HUD is publishing this Notice to identify Federal buildings and other real property that HUD has reviewed for suitability for use to assist the homeless. The properties were reviewed using information provided to HUD by Federal landholding agencies regarding unutilized and underutilized buildings and real property controlled by such agencies or by GSA regarding its inventory of excess or surplus Federal property. This Notice is also published in order to comply with the December 12, 1988 Court Order in *National Coalition for the Homeless* v. *Veterans Administration*, No. 88–2503–OG (D.D.C.).

Properties reviewed are listed in this Notice according to the following categories: Suitable/available, suitable/

unavailable, suitable/to be excess, and unsuitable. The properties listed in the three suitable categories have been reviewed by the landholding agencies, and each agency has transmitted to HUD: (1) Its intention to make the property available for use to assist the homeless, (2) its intention to declare the property excess to the agency's needs, or (3) a statement of the reasons that the property cannot be declared excess or made available for use as facilities to assist the homeless.

Properties listed as suitable/available will be available exclusively for homeless use for a period of 60 days from the date of this Notice. Homeless assistance providers interested in any such property should send a written expression of interest to HHS, addressed to Brian Rooney, Division of Property Management, Program Support Center, HHS, room 5B–41, 5600 Fishers Lane, Rockville, MD 20857; (301) 443–2265. (This is not a toll-free number.) HHS will mail to the interested provider an application packet, which will include instructions for completing the application. In order to maximize the opportunity to utilize a suitable property, providers should submit their written expressions of interest as soon as possible. For complete details concerning the processing of applications, the reader is encouraged to refer to the interim rule governing this program, 24 CFR part 581.

For properties listed as suitable/to be excess, that property may, if subsequently accepted as excess by GSA, be made available for use by the homeless in accordance with applicable law, subject to screening for other Federal use. At the appropriate time, HUD will publish the property in a Notice showing it as either suitable/available or suitable/unavailable.

For properties listed as suitable/unavailable, the landholding agency has decided that the property cannot be declared excess or made available for use to assist the homeless, and the property will not be available.

Properties listed as unsuitable will not be made available for any other purpose for 20 days from the date of this Notice. Homeless assistance providers interested in a review by HUD of the determination of unsuitability should call the toll free information line at 1–800–927–7588 for detailed instructions or write a letter to Mark Johnston at the address listed at the beginning of this Notice. Included in the request for review should be the property address (including zip code), the date of publication in the **Federal Register**, the landholding agency, and the property number.

For more information regarding particular properties identified in this Notice (*i.e.*, acreage, floor plan, existing sanitary facilities, exact street address), providers should contact the appropriate landholding agencies at the following addresses: AIR FORCE: Ms. Barbara Jenkins, Air Force Real Estate Agency, (Area—MI), Bolling Air Force Base, 112 Luke Avenue, Suite 104, Building 5683, Washington, DC 20332–8020; (202) 767–4184; COE: Mr. Robert Swieconek, Army Corps of Engineers, Management & Pulaski Building, Room 4224, 20 Massachusetts Avenue, NW, Washington, DC 20314–1000; (202) 761–1749: ENERGY: Ms. Marsha Penhaker, Department of Energy, Facilities Planning and Acquisition Branch, FM–20, Room 6H–058, Washington, DC 20585; (202) 586–0426; GSA: Mr. Brian K. Polly, Assistant Commissioner, General Services Administration, Office of Property Disposal, 18th and F Streets, NW, Washington, DC 20405; (202) 501–2059; NAVY: Mr. Charles C. Cocks, Department of the Navy, Director, Real Estate Policy Division, Naval Facilities Engineering Command, Code 241A, 200 Stovall Street, Alexandria, VA 22332–2300; (703) 325–7342; (These are not toll-free numbers).

Dated: October 9, 1997.

Fred Karnas, Jr.,

Deputy Assistant Secretary for Economic Development.

Title V, Federal Surplus Property Program Federal Register Report for 10/17/97

Suitable/Available Properties

Buildings (by State)

Hawaii

Bldg. 5421
Iroquois Point Housing
Navy Public Works Center
Ewa Beach Co: Honolulu HI 96706–
Landholding Agency: Navy
Property Number: 779740002
Status: Excess
Comment: 1543 sq. ft., concrete/wood, possible asbestos/lead paint, off-site use only (may not be feasible)

Bldg. 5423
Iroquois Point Housing
Navy Public Works Center
Ewa Beach Co: Honolulu HI 96706–
Landholding Agency: Navy
Property Number: 779740003
Status: Excess
Comment: 336 sq. ft., concrete/wood, possible asbestos/lead paint, off-site use only (may not be feasible)

Bldg. 5425
Iroquois Point Housing
Navy Public Works Center
Ewa Beach Co: Honolulu HI 96706–
Landholding Agency: Navy
Property Number: 779740004
Status: Excess
Comment: 1543 sq. ft., concrete/wood, possible asbestos/lead paint, off-site use only (may not be feasible)

Bldg. 5427
Iroquois Point Housing
Navy Public Works Center
Ewa Beach Co: Honolulu HI 96706–
Landholding Agency: Navy
Property Number: 779740005
Status: Excess
Comment: 336 sq. ft., concrete/wood, possible asbestos/lead paint, off-site use only (may not be feasible)

Bldg. 5429
Iroquois Point Housing
Navy Public Works Center
Ewa Beach Co: Honolulu HI 96706–
Landholding Agency: Navy
Property Number: 779740006
Status: Excess
Comment: 1543 sq. ft., concrete/wood, possible asbestos/lead paint, off-site use only (may not be feasible)

Bldg. 5431
Iroquois Point Housing
Navy Public Works Center
Ewa Beach Co: Honolulu HI 96706–
Landholding Agency: Navy
Property Number: 779740007
Status: Excess
Comment: 336 sq. ft., concrete/wood, possible asbestos/lead paint, off-site use only (may not be feasible)

Missouri

Riverlands Ofc. Bldg.
Melvin Price Locks & Dam
Access Road
West Alton Co: St. Charles MO 63386–
Landholding Agency: COE
Property Number: 319730001
Status: Excess
Comment: 5000 sq. ft., most recent use—office, flood damaged, off-site use only

New Jersey

ESMT Manasquan
124 Ocean Ave.
Manasquan Co: Monmouth NJ
Landholding Agency: GSA
Property Number: 549730025
Status: Excess
Comment: main bldg. (5714 sq. ft.), paint locker (96 sq. ft.), garage (3880 sq. ft.), need repairs, presence of asbestos/lead paint, Coast Guard easement
GSA Number: 1–U–NJ–0632

New York

Stockton School/Maint Garage
Mill Street
Stockton NY 14784–
Landholding Agency: GSA
Property Number: 549730024
Status: Excess
Comment: 13,555 sq. ft., 1-story, most recent use—training center, 4.8 acres of land
GSA Number: 1–L–NY–0860

Suitable/Unavailable Properties

Buildings (by State)

Colorado

Bldg. 8026
U.S. Air Force Academy
Colorado Springs Co: El Paso CO 80814–2400
Landholding Agency: Air Force

Property Number: 189730009
Status: Underutilized
Comment: heat plant, 4-story

Bldg. 9023
U.S. Air Force Academy
Colorado Springs Co: El Paso CO 80814–2400
Landholding Agency: Air Force
Property Number: 189730010
Status: Underutilized
Comment: 4112 sq. ft., most recent use—preschool

Bldg. 9027
U.S. Air Force Academy
Colorado Springs Co: El Paso CO 80814–2400
Landholding Agency: Air Force
Property Number: 189730011
Status: Underutilized
Comment: 4112 sq. ft., most recent use—child care center

Bldg. 9214
U.S. Air Force Academy
Colorado Springs Co: El Paso CO 80814–2400
Landholding Agency: Air Force
Property Number: 189730012
Status: Underutilized
Comment: 1403 sq. ft., most recent use—aero club

Land (by State)

Texas

Parcel #222
Lake Texoma Co: Grayson TX
Location: C. Meyerheim survey A–829 J. Hamilton survey A–529
Landholding Agency: COE
Property Number: 319010421
Status: Excess
Comment: 52.80 acres; most recent use—recreation

Unsuitable Properties

Buildings (by State)

Delaware

Mispillion River Light
Milford Co: Sussex DE 19963–
Landholding Agency: GSA
Property Number: 549740001
Status: Excess
Reason: Extensive deterioration
GSA Number: 4–U–DE–461

Florida

Sigsbee Park Annex (174 units)
Naval Air Station
Key West Co: Monroe FL 33043–
Landholding Agency: Navy
Property Number: 779740001
Status: Unutilized
Reason: Extensive deterioration

Idaho

STF Area, Natl Eng & Env Lab
#601, 607, 612, 501, 502, ARA–628
Scoville Co: Butte ID 83415–
Landholding Agency: Energy
Property Number: 419740003
Status: Excess
Reason: Extensive deterioration

New Jersey

Bldg. 329
Naval Air Engineering Station
Lakehurst Co: Ocean NJ 08733–5000
Landholding Agency: Navy
Property Number: 779740008
Status: Unutilized
Reason: Extensive deterioration

Bldg. 116
Naval Air Engineering Station
Lakehurst Co: Ocean NJ 08733–5000
Landholding Agency: Navy
Property Number: 779740009
Status: Unutilized
Reason: Extensive deterioration

Ohio

GP–5, MEMP Site
Miamisburg Co: Montgomery OH 45343–
Landholding Agency: Energy
Property Number: 419740001
Status: Excess
Reason: Within 2000 ft. of flammable or explosive material

Mound Site, MEMP
Miamisburg Co: Montgomery OH 45343–
Landholding Agency: Energy
Property Number: 419740002
Status: Unutilized
Reason: Within 2000 ft. of flammable or explosive material Secured Area

Virginia

Fleet Training Center
Fire Fighting Training Facility
SDA–323, SDA–324, SDA–325, SDA–326
Norfolk VA 23511–
Landholding Agency: Navy
Property Number: 779740010
Status: Unutilized
Reason: Extensive deterioration

[FR Doc. 97–27344 Filed 10–16–97; 8:45 am]

BILLING CODE 4210–29–M

INTER-AMERICAN FOUNDATION

Sunshine Act Meeting; Inter-American Foundation Board Meeting

TIME AND DATE: 11:30 a.m.–3:00 p.m., October 29, 1997.

PLACE: 901 N. Stuart Street, Tenth Floor, Arlington, Virginia 22203.

STATUS: Open Session.

MATTERS TO BE CONSIDERED:

1. Approval of the Minutes of the July 17, 1997, Meeting of the Board of Directors.
2. Chair's Report.
3. Swearing-in of New Board Members.
4. President's Report.
5. Executive Session to Discuss Personnel Issues.

CONTACT PERSON FOR MORE INFORMATION: Adolfo A. Franco, Secretary to the Board of Directors, (703) 841–3894.

Dated: October 14, 1997.

Adolfo A. Franco,

Sunshine Act Officer.

[FR Doc. 97–27754 Filed 10–15–97; 3:40 pm]

BILLING CODE 7025–01–M

DEPARTMENT OF THE INTERIOR

Office of the Secretary

Notice of Meeting

SUMMARY: The Department of the Interior, Office of the Secretary is announcing a public meeting of the Exxon Valdez Oil Spill Public Advisory Group.

DATES: November 4–5, 1997, at 8:30 a.m.

ADDRESS: Fourth floor conference room, 645 ''G'' Street, Anchorage, Alaska.

FOR FURTHER INFORMATION CONTACT: Douglas Mutter, Department of the Interior, Office of Environmental Policy and Compliance, 1689 ''C'' Street, Suite 119, Anchorage, Alaska, (907) 271–5011.

SUPPLEMENTARY INFORMATION: The Public Advisory Group was created by Paragraph V.A.4 of the Memorandum of Agreement and Consent Decree entered into by the United States of America and the State of Alaska on August 27, 1991, and approved by the United States District Court for the District of Alaska in settlement of *United States of America* v. *State of Alaska*, Civil Action No. A91–081 CV. The agenda will include a discussion of the restoration reserve fund.

Willie R. Taylor,

Director, Office of Environmental Policy and Compliance.

[FR Doc. 97–27517 Filed 10–16–97; 8:45 am]

BILLING CODE 4310–RG–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Summary of Incidental Take Permits Issued by the Southeast Region of the U.S. Fish and Wildlife Service Pursuant to the Authority of Section 10(a)(1)(B) of the Endangered Species Act

AGENCY: Fish and Wildlife Service, Interior

ACTION: Notice.

SUMMARY: The Southeastern Regional office of the Fish and Wildlife Service (Service) is providing notice of issued permits which incidentally take threatened and endangered species pursuant to Section 10(a)(1)(B) of the Endangered Species Act of 1973 (Act) (16 U.S.C. 1531–1536) and the Service's implementing regulations governing listed fish, wildlife, and plant permits (50 CFR parts 13 and 17).

Issuance of these permits, as required by the Act, was based on findings that such permits: (1) Were applied for in good faith; (2) will not operate to the

disadvantage of the listed species which are the subject of the permit, and; (3) are consistent with the purposes and policies set forth in Section 2 of the Act. Each permit issued was also found in compliance with and are subject to parts 13 and 17 of Title 50 CFR, the Service's regulations governing listed species permits.

ADDRESSES: Persons wishing to review any of the issued permits or accompanying documents may obtain a copy by writing the Service's Southeast Regional Office, Atlanta, Georgia. Documents will also be available for public inspection by appointment during normal business hours at the Regional Office, 1875 Century Boulevard, Suite 200, Atlanta, Georgia 30345 (Attn: Endangered Species Permits). Please reference the applicable permit number when requesting the documents.

FOR FURTHER INFORMATION CONTACT: Mr. Rick G. Gooch, Regional Permit Coordinator, (see **ADDRESSES** above), telephone: 404/679–7110.

SUPPLEMENTARY INFORMATION: The following is a listing of issued permits. Each entry identifies permit number, the Applicant's name, the species for which incidental taking was sought, the location of the activity, and the date the permit was issued.

Permit Number: 800149.
Applicant: Red Oak Timber Company.
Species: Red-cockaded woodpecker.
Project Location: Vernon Parish, Louisiana.
Date Issued: July 17, 1995.

Permit Number: 804465.
Applicant: Pinebelt Regional Landfill Authority.
Species: Gopher tortoise.
Project Location: Perry County, Mississippi .
Date Issued: September 22, 1995.

Permit Number: 804465.
Applicant: Jack Primus Partners, LLC.
Species: Red-cockaded woodpecker.
Project Location: Berkeley County, South Carolina .
Date Issued: October 24, 1995.

Permit Number: 802986.
Applicant: Martinique Developers, LLC.
Species: Alabama beach mouse.
Project Location: Baldwin County, Alabama .
Date Issued: January 26, 1996.

Permit Number: 807952.
Applicant: Potlatch Corporation.
Species: Red-cockaded woodpecker.
Project Location: Bradley and Calhoun Counties, Arkansas .
Date Issued: February 28, 1996.

Permit Number: 810934.
Applicant: Gasque/Felkel.
Species: Red-cockaded woodpecker.
Project Location: Orangeburg County, South Carolina .
Date Issued: March 29, 1996.

Permit Number: 809898.
Applicant: Brett Real Estate Developments, Inc..
Species: Alabama beach mouse.
Project Location: Baldwin County, Alabama .
Date Issued: April 8, 1996.

Permit Number: 806150.
Applicant: Joseph A. Hill.
Species: Florida scrub jay.
Project Location: Brevard County, Florida .
Date Issued: April 16, 1996.

Permit Number: 811415.
Applicant: Macmillan Blowdel.
Species: Red hills salamander.
Project Location: Monroe and Conecuh Counties, Alabama .
Date Issued: April 26, 1996.

Permit Number: 811416.
Applicant: Sage Development.
Species: Alabama beach mouse.
Project Location: Baldwin County, Alabama.
Date Issued: May 15, 1996.

Permit Number: 800150.
Applicant: Waterside Down Development Corporation.
Species: Florida scrub jay.
Project Location: Brevard County, Florida.
Date Issued: May 21, 1996.

Permit Number: 811902.
Applicant: Woolbright Venture.
Species: Florida scrub jay.
Project Location: Indian River County, Florida.
Date Issued: July 10, 1996.

Permit Number: 809072.
Applicant: Weyerhaeuser Company.
Species: American burying beetle.
Project Location: McCurtain County, Oklahoma, and Little River County, Arkansas.
Date Issued: July 11, 1996.

Permit Number: 808474.
Applicant: Windover Farms/Pineda Crossing.
Species: Red-cockaded woodpecker.
Project Location: Brevard County, Florida.
Date Issued: August 1, 1996.

Permit Number: 816491.
Applicant: Ben Cone.
Species: Red-cockaded woodpecker.
Project Location: Pender County, North Carolina.
Date Issued: October 2, 1996.

Permit Number: 816732.
Applicant: Snow Construction, Inc.
Species: Bald eagle.
Project Location: Osceola County, Florida.
Date Issued: October 22, 1996.

Permit Number: 819363.
Applicant: Collins-Miller.
Species: Alabama beach mouse/sea turtles.
Project Location: Baldwin County, Alabama.
Date Issued: November 8, 1996.

Permit Number: 811813.
Applicant: Volusia County Government.
Species: Sea turtles.
Project Location: Coastline of Volusia County, Florida.
Date Issued: November 21, 1996.

Permit Number: 816555.
Applicant: Plantation Palms.
Species: Alabama beach mouse and nesting sea turtles.
Project Location: Baldwin County, Alabama.
Date Issued: November 27, 1996.

Permit Number: 819464.
Applicant: Fort Morgan Paradise Joint Venture.
Species: Alabama beach mouse and nesting sea turtles.
Project Location: Baldwin County, Alabama.
Date Issued: December 9, 1996.

Permit Number: 821527.
Applicant: Union Camp Corporation.
Species: Red hills salamander.
Project Location: Butler, Conecuh, Covington, and Crenshaw Counties, Alabama.
Date Issued: January 8, 1997.

Permit Number: 821992.
Applicant: Mulaski.
Species: Alabama beach mouse.
Project Location: Baldwin County, Alabama.
Date Issued: January 22, 1997.

Permit Number: 824543.
Applicant: Wilmon Timber Company.
Species: Red hills salamander.
Project Location: Monroe County, Alabama.
Date Issued: March 19, 1997.

Permit Number: 822026.
Applicant: Charles Ingram Lumber Company.
Species: Red-cockaded woodpecker.
Project Location: Florence County, South Carolina.
Date Issued: April 14, 1997.

Permit Number: 811416 Amendment #1.
Applicant: Sage Development.
Species: Alabama beach mouse.
Project Location: Baldwin County, Alabama.
Date Issued: May 5, 1997.

Permit Number: 827374.
Applicant: Friendfield Plantation, Inc.
Species: Red-cockaded woodpecker.
Project Location: Georgetown County, South Carolina.

Date Issued: July 21, 1997.
Permit Number: 829937.
Applicant: Holnam Inc./HCR Limestone Inc.
Species: Red-cockaded woodpecker.
Project Location: Citrus and Alachua Counties, Florida.
Date Issued: August 21, 1997.
Permit Number: 832536.
Applicant: E.J. Mouhot.
Species: Florida scrub jay.
Project Location: Charlotte County, Florida.
Date Issued: September 29, 1997.

Dated: October 10, 1997.

Judy L. Jones,

Acting Regional Director.

[FR Doc. 97–27573 Filed 10–16–97; 8:45 am].

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[1020–04 MT–001-EA97]

Final Supplementary Rule Requiring the Use of Certified Noxious Weed Seed-Free Forage on Public Lands in Montana and the Availability of the Environmental Assessment, Decision Record, and Finding of No Significant Impact for Implementation of Requirements for Weed Seed-Free Forage on Public Lands in the Bureau of Land Management; Montana

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: The Montana State Office of the Bureau of Land Management (BLM) recently prepared an environmental assessment (EA) documenting the analysis of two alternatives for managing noxious weeds on public lands in Montana. The EA's proposed action consisted of a supplementary rule under 43 CFR 8365.1–6 to require the use of certified noxious weed seed-free forage on those public lands. Forage subject to this rule would include hay, grains, cubes, pelletized feeds, straw, and mulch. The State Director of the BLM's Montana State Office has issued a decision record that the EA's proposed action and supplemental rule will not have any significant impact on the human environment and that an environmental impact statement is not required.

Therefore, the State Director is requiring that public land users, including permittees and local, state, or federal government agents conducting administrative activities, use certified noxious weed seed-free forage on BLM-administered public lands in Montana.

Six people commented on the Proposed Supplementary Rule Requiring the Use of Certified Noxious Weed Seed-Free Forage on Public Lands in Montana, placed in the **Federal Register** dated March 28, 1997. The comments are covered in the USDI, 43CFR4130.0–2, October 1, 1996, concerning supplemental feeding on BLM-administered lands.

Montana encompasses approximately 8,069,002 acres of public land administered by BLM. This rule will affect public land users who use hay or other forage products on the BLM-administered public lands in Montana such as recreationists using pack and saddle stock, ranchers with grazing permits, outfitters, and contractors who use straw or other mulch for reclamation purposes. These individuals or groups would be required to use only certified noxious weed seed-free forage products, while on BLM-administered public lands in Montana.

EFFECTIVE DATES: The rule will become effective November 17, 1997 and will remain in effect until modified or rescinded by the Authorized Officer.

FOR FURTHER INFORMATION CONTACT: Hank McNeel, Weed Management Specialist, BLM Montana State Office, P.O. Box 36800, Billings, MT 59107, 406 255–2931.

SUPPLEMENTARY INFORMATION: The EA is consistent with the land use plans for Montana BLM.

Noxious and undesirable weeds are a serious problem in the western United States. Estimates of the rapid spread of weeds in the West include 2,300 acres per day on BLM-administered public lands and 4,600 acres per day on all federally-administered land in the West. Species such as leafy spurge, spotted knapweed, Russian knapweed, musk thistle, dalmatian toadflax, purple loosestrife, houndstoungue, and other non-native noxious and undesirable weeds have no natural controls to keep their populations in balance. Consequently, these weeds invade healthy ecosystems, displace native vegetation, reduce species diversity, and damage wildlife habitat. Widespread infestations lead to soil erosion and stream sedimentation. Furthermore, noxious weed invasions weaken revegetation efforts, reduce livestock and wildlife grazing capacity, occasionally affect the health of public land users by aggravating allergies and other ailments, and threaten federally-protected or native plants and animals.

To help reduce the spread of noxious weeds, a number of Western States are jointly developing noxious weed-free or weed seed-free forage certification standards, and, in cooperation with various federal, state, and county agencies, passed weed management laws. Because hay and other forage products containing noxious weed seed are part of the infestation problem, Montana has developed the Montana Noxious Weed Seed Free Forage Program and the Regional Weed Free Forage Certification Standards for crop inspection; a certification-identification process; participates in a regional inspection certification-identification process; and encourages forage producers in Montana to grow noxious weed seed-free products and have them certified.

Region I of the United States Forest Service, Department of Agriculture, implemented a similar policy for all National Forest lands in Montana in 1997. This proposal will provide a standard regulation for all users of BLM-administered public lands in the Montana and will provide for coordinated and consistent management with the U.S. Forest Service.

In cooperation with the State of Montana and the U.S. Forest Service, Montana State Office is implementing a ban of the use of forage that has not been certified, on all BLM-administered lands within Montana. This proposal includes public information to insure that: (1) this ban is well publicized and understood, and (2) visitors to and land users of public lands administered by the Montana BLM will know where they can purchase state-certified hay and other forage products.

These supplementary rules will not appear in the Code of Federal Regulations. The principal author of these supplementary rules is Hank McNeel, Weed Management Specialist, BLM Montana State Office.

For the reasons stated above, under the authority of 43 Code of Federal Regulations 8365.1–6, the Montana State Director issues supplementary rules to read: Supplementary Rules to Require the Use of Certified Noxious Weed Seed-Free Forage on Bureau of Land Management-Administered Public Lands in Montana.

1. To help prevent the spread of weeds on BLM-administered lands in Montana, shall be closed to possessing, transporting or storing hay, grain, cubed or pelletized products, straw, and mulch that has not been certified as free of noxious weed seed.

2. Certification will comply with ''Montana Noxious Weed Seed Free Forage Program and the Regional Weed Free Forage Certification Standards Procedures Manual for Certification of: Hay, Pellets, Mulch, Straw, Cubes and Feeds by the State of Montana

Department of Agriculture, Helena, Montana, April 1, 1997.

3. The possession or storage of hay, grain, straw, or cubedor pelletized products that have an identifiable label as being certified Noxious Weed and/or Noxious Weed Seed-Free by an authorized State or County Department of Agriculture Official; the authorizing State must be recognized as having a Noxious Weed Certification Program for agronomic products; each individual bale or container must be tagged or marked as weed or weed seed-free and reference the written certification.

4. The following persons are exempt from this order: (1) Any person with a permit signed by an authorized officer of the BLM's Montana State Office or field offices within Montana, specifically authorizing the prohibited act or omission within that resource area; (2) Persons transporting forage products on Federal and State Highways and County roads that are not BLM Development Road or Trails.

5. Any person who knowingly and willfully violates the provisions of these supplemental rules may be commanded to appear before a designated United States Magistrate and may be subject to a fine of not more than $1,000 or imprisonment of not more than 12 months, or both, as defined in 43 United States Code 1733(a).

Dated: October 3, 1997.

Thomas P. Lonnie,

Deputy State Director, Division of Resources.

[FR Doc. 97–27327 Filed 10–16–97; 8:45 am]

BILLING CODE 4310–DN–P

DEPARTMENT OF THE INTERIOR

[CA–350–1230–00]

Notice of Intent To Prepare Land Use Plan Amendment

AGENCY: Bureau of Land Management, Department of the Interior, Eagle Lake Resource Area, California.

SUMMARY: This is a Notice of Intent to Prepare a Land Use Plan Amendment for the Fort Sage OHV Area. The planning process to date included scoping, a public meeting and development of an Environmental Assessment for revised OHV designations. This Notice of Intent is specifically to amend the Honey Lake/Beckwourth Management Framework Plan of 1976.

PUBLIC PARTICIPATION: Scoping commended on May 20, 1996. A public meeting was held June 12, 1996 in Susanville, California. All comments received since scoping commenced and during the public meetings, are being considered in this process.

SUPPLEMENTARY INFORMATION: The Honey Lake/Beckwourth Management Framework Plan is in the area of the Northwest Great Basin in Southeastern Lassen County, California. The scoping, and public participation covers the whole of the Fort Sage OHV Area. This draft plan amendment for the Honey Lake/Beckwourth Management Framework Plan is scheduled for completion in late December, 1997.

FOR FURTHER INFORMATION OR RELATED DOCUMENTS CONTACT: Linda Hansen, Area Manager, Eagle Lake Resource Area, 2950 Riverside Drive, Susanville, California 96130. Telephone: (916) 257–0456.

Linda Hansen,

Area Manager.

[FR Doc. 97–27616 Filed 10–16–97; 8:45 am]

BILLING CODE 4310–40–M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[OR–050–1020–00: GP8–0010]

Notice of Meeting of John Day-Snake Resource Advisory Council

October 7, 1997.

AGENCY: Bureau of Land Management, Prineville District.

ACTION: Meeting of John Day-Snake Resource Advisory Council: Pendleton, Oregon; November 24, 1997.

SUMMARY: A meeting of the John Day-Snake Resource Advisory Council will be held on November 24, 1997 from 8:00 am to 5:00 pm, at the Double Tree Inn, 304 SE Nye Ave, Pendleton, Oregon. The meeting is open to the Public. Public comments will be received at 1:00 pm. Topics to be discussed by the council include the Interior Columbia Basin Ecosystem Management Project, Standards for Rangeland Health and Guidelines for Livestock Grazing on public lands, development of a John Day River Management Plan, and an update on significant land exchanges within the council's geographic area.

FOR FURTHER INFORMATION CONTACT: James L. Hancock, Bureau of Land Management, Prineville District Office, 3050 NE Third Street, Prineville, Oregon 97754, or call 541–416–6700.

Dated: October 7, 1997.

James L. Hancock,

District Manager.

[FR Doc. 97–27537 Filed 10–16–97; 8:45 am]

BILLING CODE 4310–33–M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[UT–912–08–0777–52]

Notice of Meeting

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of meeting of the Utah Resource Advisory Council.

SUMMARY: A meeting of the Utah Resource Advisory Council (RAC) will be held November 7, 1997, from 8:00 a.m. until 3:00 p.m. at the Provo Park Hotel, 101 West 100 North in Provo, Utah. The purpose of this meeting is to review and accept, by the RAC, the fire rehab methods and policies which will then be submitted to the State Director for implementation. We will also discuss recreation issues across the state.

Resource Advisory Council meetings are open to the public; however, transportation, meals, and overnight accommodations are the responsibility of the participating public. A public comment period has been scheduled from 2:30–3:00 p.m.

FOR FURTHER INFORMATION: Anyone interested in attending the meeting or wanting to address the Council, should contact Sherry Foot at the Bureau of Land Management, Utah State Office, 324 South State Street, Salt Lake City, Utah, 84111 or by calling (801) 539–4195.

Dated: October 9, 1997.

Ted Stephenson,

Acting. State Director.

[FR Doc. 97–27575 Filed 10–16–97; 8:45 am]

BILLING CODE 4310–DQ–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[CO–010–07–1020–00–241A]

Northwest Colorado Resource Advisory Council Meeting

AGENCY: Bureau of Land Management, Interior

ACTION: Notice of meeting.

SUMMARY: The next meetings of the Northwest Colorado Resource Advisory Council will be held on Friday, November 7, 1997, in Eagle, Colorado.

DATES: Friday, November 7, 1997.

ADDRESSES: For further information, contact Joann Graham, Bureau of Land Management (BLM), Grand Junction District Office, 2815 H Road, Grand Junction, Colorado 81506; Telephone (970) 244–3037.

SUPPLEMENTARY INFORMATION: The meeting will be held at the Eagle Municipal Library, 600 Broadway, Eagle, Colorado. Agenda items include the introduction of the new BLM Colorado State Director, subcommittee reports, and wilderness inventory update.

All resource advisory council meetings are open to the public. Interested persons may make oral statements at the meetings or submit written statements following the meetings. Per-person time limits for oral statements may be set to allow all interested persons an opportunity to speak.

Summary minutes of council meetings are maintained in both the Grand Junction and Craig District Offices. They are available for public inspection and reproduction during regular business hours within thirty (30) days following the meeting.

Dated: October 9, 1997.

Mark T. Morse,

Grand Junction/Craig District Manager.

[FR Doc. 97–27611 Filed 10–16–97; 8:45 am]

BILLING CODE 4310–70–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[NM–010–1430–01; NMNM 94904/G–010-G7–0252]

Public Land Order No. 7291; Withdrawal of Public Lands and Federal Minerals to Allow Sale of Humate; New Mexico

AGENCY: Bureau of Land Management, Interior.

ACTION: Public land order.

SUMMARY: This order withdraws 1,188.30 acres of public lands from surface entry and mining, and 988.40 acres of federally reserved mineral interests underlying private surface estate from mining, for a period of 20-years, for the Bureau of Land Management to protect an area having potential for development of humate (a carbonaceous shale) from encumbrances due to mining claim location. The lands have been and will remain open to mineral leasing.

EFFECTIVE DATE: October 17, 1997.

FOR FURTHER INFORMATION CONTACT: Debby Lucero, BLM Rio Puerco Resource Area Office, 435 Montano Road NE, Albuquerque, New Mexico 87107, 505–761–8787.

By virtue of the authority vested in the Secretary of the Interior by Section 204 of the Federal Land Policy and Management Act of 1976, 43 U.S.C. 1714 (1994), it is ordered as follows:

1. Subject to valid existing rights, the following described public lands are hereby withdrawn from settlement, sale, location, or entry under the general land laws, including the United States mining laws (30 U.S.C. Ch. 2 (1994)), but not from leasing under the mineral leasing laws, to protect an area having potential for development of humate (a carbonaceous shale) from encumbrances due to mining claim location:

New Mexico Principal Meridian

T. 19 N., R. 1 W.,
Sec. 4, lots 1 and 3, S½NE¼, SE¼NW¼, E½SW¼, and SE¼;
Sec. 10, W½W½SW¼;
Sec. 17, E½E½SE¼;
Sec. 20, NE¼, N½SW¼, and NW¼SE¼.
T. 20 N., R. 1 W.,
Sec. 27, S½N½, NE¼SW¼, S½SW¼, and N½SE¼;
Sec. 33, NW¼SW¼.

The areas described aggregate 1,188.30 acres in Sandoval County.

2. Subject to valid existing rights, the federally reserved mineral interests in the following described lands are hereby withdrawn from the United States mining laws (30 U.S.C. Ch. 2 (1994)), but not from leasing under the mineral leasing laws, to protect an area having potential for development of humate (a carbonaceous shale) from encumbrances due to mining claim location:

New Mexico Principal Meridian

T. 19 N., R. 1 W.,
Sec. 3, lot 3, SW¼NW¼, and W½SW¼;
Sec. 4, lot 2; sec. 9, E½, and E½W½;
Sec. 21, NE¼.
T. 20 N., R. 1 W.,
Sec. 33, NE¼SW¼, and S½SW¼;
Sec. 34, W½W½SW¼.

The areas described aggregate 988.40 acres in Sandoval County.

3. The surface estate of the lands described in paragraph 2 is non-Federal. If the United States subsequently acquires these lands, the lands will be subject to the terms and conditions of this withdrawal.

4. The withdrawal made by this order does not alter the applicability of those public land laws governing the use of the lands under lease, license, or permit, or governing the disposal of their mineral or vegetative resources other than under the mining laws.

5. This withdrawal will expire 20 years from the effective date of this order unless, as a result of a review conducted before the expiration date pursuant to Section 204(f) of the Federal Land Policy and Management Act of 1976, 43 U.S.C. 1714(f) (1994), the Secretary determines that the withdrawal shall be extended.

Dated: October 9, 1997.

Bob Armstrong,

Assistant Secretary of the Interior.

[FR Doc. 97–27587 Filed 10–16–97; 8:45 am]

BILLING CODE 4310–AG–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[AZ–050–08–1430–01; AZA 30301]

Arizona: Notice of Reality Action; Classification of Public Land for Recreation and Public Purposes Lease or Conveyance, La Paz County, AZ

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of reality action.

SUMMARY: The following described public lands in La Paz County have been examined and found suitable for classification for lease or conveyance under the provisions of the Recreation and Public Purposes Act, as amended (43 U.S.C. 869 *et seq.*):

Gila and Salt River Meridian, Arizona

T. 1 S., R. 23 W.,
Sec. 5, portion of lot 8.
Containing 4.65 acres, more or less.

SUPPLEMENTARY INFORMATION: La Paz County has filed a Recreation and Public Purposes Act application for a park and interpretative historic museum that would be located near the community of Cibola, approximately 3 miles east of the Colorado River. This facility is needed in order to serve the public demand for both day use park facilities and cultural facilities. The lands are not needed for Federal purposes. Lease or conveyance is consistent with current Bureau of Land Management land use planning and would be in the public interest.

The lease/patent, when issued, will be subject to the following terms, conditions, and reservations:

1. Provisions of the Recreation and Public Purposes Act and to all applicable regulations of the Secretary of the Interior.

2. A right-of-way for ditches and canals constructed by the authority of the United States.

3. All minerals shall be reserved to the United States, together with the right to prospect for, mine, and remove minerals.

4. All valid existing rights documented on the official public land records at the time of lease issuance.

5. Any other reservations that the authorized officer determines appropriate to ensure public access and

proper management of Federal lands and interests therein.

Upon publication of this notice in the **Federal Register**, the land will be segregated from all other forms of appropriation under the public land laws, including the general mining laws, except for lease or conveyance under the Recreation and Public Purposes Act and leasing under the mineral leasing laws. For a period of 45 days from the date of publication of this notice in the **Federal Register**, interested parties may submit comments regarding the proposed lease or classification of the lands to the Field Manager, Yuma Field Office, 2555 E. Gila Ridge Road, Yuma, Arizona 85365.

Classification Comments

Interested parties may submit comments involving the suitability of the land for a park and museum. Comments on the classification are restricted to whether the land is physically suited for the proposal, whether the use will maximize the future use or uses of the land, whether the use is consistent with local planning and zoning, or if the use is consistent with State and Federal programs.

Application Comments

Interested parties may submit comments regarding the specific use proposed in the application and plan of development, whether the Bureau of Land Management followed proper administrative procedures in reaching the decision, or any other factor not directly related to the suitability of the land for a park and museum.

EFFECTIVE DATE: Any adverse comments will be reviewed by the Arizona State Director. In the absence of any adverse comments, the classification will become effective December 16, 1997. The lands will not be offered for lease until the classification becomes effective.

FOR FURTHER INFORMATION CONTACT: Reality Specialist Lucas Lucero, Yuma Field Office, 2555 East Gila Ridge Road, Yuma AZ 85365, telephone (520) 317–3215.

Dated: October 8, 1997.

Gail Acheson,

Field Manager.

[FR Doc. 97–27610 Filed 10–16–97; 8:45 am]

BILLING CODE 4310–32–M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[CA–016–1220–00]

Supplementary Rules for Public Lands in the Carrizo Plain Natural Area, California

AGENCY: Bureau of Land Management, Interior.

ACTION: Establishment of Supplementary Rules relating to shooting, access, vehicle use, camping, and resource protection within the Carrizo Plain Natural Area in San Luis Obispo and Kern Counties, California.

SUMMARY: The Caliente Resource Area hereby gives notice and establishes the following closures and Special and Supplementary Rules for the Carrizo Plain Natural Area (CPNA) effective as of the date of this publication, as provided for under Title 43, Code of Federal Regulations, Subparts 8341.2, 8364.1, and 8365.1–6:

A. Public lands within ¼ mile of any campground, Painted Rock, administrative facility (including the Washburn, Saucito, Goodwin, and MU ranch headquarters), and all developed overlooks, interpretive sites or pullouts, are closed to the discharge of firearms. Public lands within the Painted Rock ''no shooting zone'' are posted with signs at the most prominent points of public access. The boundaries of this closure are described in the CPNA Management Plan and are available from the Bakersfield District BLM Office. Those exempted from this closure order include law enforcement officers in the commission of their official duties. These closures are for the purpose of enhancing public safety and will also decrease potential conflicts with recreational users.

Recreational target shooting is prohibited within the entire CPNA. Hunting is allowed on public within the CPNA where public safety is not at risk or that have not been closed to shooting. No person shall violate any federal, state or local laws pertaining to use, possession or discharge of firearms while on any BLM administered public lands. This closure governing the discharge of firearms affects approximately 5,200 acres of public lands in San Luis Obispo County. The recreational target shooting closure affects approximately 200,000 acres of public lands in San Luis Obispo and Kern Counties.

B. Certain public lands in the CPNA are subject to closure to all public use, including but not limited to vehicle operation, camping, shooting, hiking, and sightseeing. All public lands within ¼ mile of Sulfur Springs are closed to public access, except under permit from the BLM, in order to protect sensitive resources. All public lands within ¼ mile of Painted Rock are closed to public access from March 1 through July 15 each year, except for tours authorized by the Bureau of Land Management, in order to protect sensitive resources. The Washburn Administrative Site, the Goodwin Education Center, the MU, Goodwin, Saucito, and Painted Rock Ranch headquarters, and Painted Rock may be closed to public access as needed to protect these resources and facilities. This closure affects approximately 250 acres in San Luis Obispo County.

C. Operation of motor vehicles, aircraft, and boats and flotation devices of any kind, are prohibited on or within Soda Lake and any adjacent stream, channel, dry lake, and body of water. This closure affects approximately 4,300 acres in San Luis Obispo County. Exceptions may be allowed, but must be approved in advance in writing by the Authorized Officer. Law enforcement and fire protection personnel operating within the scope of their official duties are exempt from the provisions of this closure order.

D. Off-Highway vehicle use within the CPNA is limited to designated routes. Designated routes are defined as existing well traveled roads which have been identified and mapped. Maps of these routes will be made available to the public. The operation of any motorized vehicle off of designated routes of travel is prohibited within the CPNA. Open routes are available for use by all vehicle, bicycle, foot and equestrian travel. All vehicle use on routes posted or designated as closed is prohibited. Except on county roads, or unless otherwise posted, the speed limit on such open roads is 25 miles per hour. Vehicles parked adjacent to any open road must be parked as close to the road as possible without preventing passage of other vehicles. Open roads may be closed temporarily at the discretion of the BLM if necessary for safety or resource protection.

Roads or routes designated as being for administrative use only are closed to all motor vehicles except those used by employees of the BLM, the California Department of Fish and Game, or The Nature Conservancy when conducting official business. Other uses require the prior approval of the BLM. Roads designated as being for administrative use only are open to bicycles and other nonmotorized vehicles, pedestrians, and casual horse use unless otherwise posted.

This limited use designation does not apply to emergency vehicles, fire suppression and rescue vehicles, law enforcement vehicles, and other motorized vehicles specifically approved by an authorized officer of the Bureau of Land Management. The closure affects approximately 200,000 acres. A map of the open route network is available from the Bureau of Land Management, 3801 Pegasus Dr., Bakersfield, CA 93308, (805) 391–6000.

E. Overnight camping is allowed within designated campgrounds and designated camping areas in the CPNA. All other public lands within the CPNA are closed to overnight parking or camping. Camping or overnight parking within all portions of the CPNA is prohibited within 200 yards of any natural or artificial water source. Overnight camping is limited to 14 days within any 30 day period, for a total of no more than 28 days within any one year period, except as specified in writing by the authorized officer.

The primary purpose of all corrals, loading chutes, and other appurtenant livestock facilities during the authorized grazing season will be for livestock management. Camping or parked vehicles may not interfere with their use. All litter, waste, and refuse at campsites must be kept within a container or receptacle while camping, and removed when leaving the CPNA.

F. Other supplemental rules prescribed by the CPNA Management Plan include:

—Property left unattended for more than three days without the prior approval of the Authorized Officer will be treated as abandoned and may be removed and stored by law enforcement personnel at the owner's expense.

—Pets and pack animals must be controlled by the owner at all times. Pack animals shall be within corrals, or adequately restrained. Pets must be prevented from chasing, harassing, or taking wildlife.

—Organized groups with 20 or more persons or 5 or more vehicles must secure a permit for any activities off county roads.

—The use of metal detectors is prohibited, except for approved administrative purposes.

—All research and study activities require a permit or written authorization from the BLM.

EFFECTIVE DATE: These rules are effective October 17, 1997 and will remain in effect until revised, revoked or amended by the Authorized Officer.

SUPPLEMENTARY INFORMATION: The above supplementary rules are being implemented for the following purposes:

The BLM administers approximately 200,000 acres in the Carrizo Plain Natural Area (CPNA). The CPNA is managed jointly with the California Department of Fish and Game and The Nature Conservancy for the benefit of indigenous species within a fully functional ecosystem. The natural area is important to fifteen species of plants and animals that are currently listed, proposed to be listed, or fully protected by either the federal or California Endangered Species Acts. In addition, the natural area encompasses world-class archaeological sites, and continues to be of great importance to native peoples. These values have contributed toward making the CPNA an increasingly popular destination for sightseeing and outdoor recreation. Use is concentrated at certain sites and along trails, but many activities are highly dispersed. The purpose of these actions is to protect and efficiently manage these special resources, and enhance visitors safety on public lands.

This order is in no way intended to affect the rights of private land owners, or their interests within the closure area, with respect to private lands. Further, this order does not infer any Bureau of Land Management jurisdiction over private or state lands within closure areas.

A copy of this **Federal Register** notice and maps showing the affected areas are available for review in the Bakersfield District Office of the Bureau of Land Management.

PENALTIES: The authorities for these closures and supplementary rules are 43 CFR 8341.2, 8364.1, and 8365.1–6. Violations of these rules are punishable by fines of up to $1,000 and/or imprisonment not to exceed 12 months as well as the penalties provided under State law.

FOR FURTHER INFORMATION CONTACT: Ronald D. Fellows, Bureau of Land Management, Bakersfield District Manager, 3809 Pegasus Dr., Bakersfield CA 93308, Phone (805) 391–6000.

Dated: October 7, 1997.

John Skibinski,

Acting District Manager.

[FR Doc. 97–27615 Filed 10–16–97; 8:45 am]

BILLING CODE 4310–40–M

DEPARTMENT OF THE INTERIOR

National Park Service

Public Notice

AGENCY: National Park Service, Interior.

ACTION: Public notice.

SUMMARY: Public notice is hereby given that the National Park Service proposes to award 17 concession permits authorizing the operation of sport hunting guide-outfitter services for the public at Wrangell St. Elias National Preserve, Alaska for a period of five years from January 1, 1998 through December 31, 2002. Currently there are sixteen concessioners providing the services described in this prospectus. One permit is for a hunt area for which there is no current operator.

EFFECTIVE DATE: December 16, 1997.

ADDRESSES: Interested parties should contact the Superintendent, Wrangell-St. Elias National Park & Preserve, P.O. Box 439, Copper Center, Alaska 99573 or by calling (907) 822–5234 for a copy of the prospectus.

SUPPLEMENTARY INFORMATION: These permits have been determined to be categorically excluded for the procedural provisions of the National Environmental Policy Act and no environmental document will be prepared.

The 16 existing concessioners have performed their obligations to the satisfication of Secretary under existing permits which expire by limitation of time on December 31, 1997, and therefore pursuant to the provisions of Section 5 of the Act of October 9, 1965 (16 U.S.C. 20), are entitled to be given preference in the renewal of the permit, providing that the existing concessioners submit a responsive offer (a timely offer which meets the terms and conditions of the Prospectus). This means that the permit will be awarded to the party submitting the best offer, provided that if the best offer was not submitted by an existing concessioner, then the existing concessioner will be afforded the opportunity to match the best offer. If the existing concession agrees to match the best offer, then the permit will be awarded to the existing concessioner. If the existing concessioner does not submit a responsive offer, the right of preference in renewal shall be considered to have been waived, and the permit will then be awarded to the party that has submitted the best responsive offer. The Secretary will consider and evaluate all offers received as a result of this notice.

There is no incumbent concessioner for the 17th permit, and accordingly, no preference will be awarded to an applicant for this guide area.

Any offer, including that of the existing concessioner, must be received by the Superintendent, Wrangell-St. Elias National Park and Preserve, P.O.

Box 439, Copper Center, AK 99573, not later than on or before the sixtieth (60th) day following publication of this notice to be considered and evaluated.

Judith Gottieb,

Acting Regional Director, Alaska Region.

[FR Doc. 97–27590 Filed 10–16–97; 8:45 am]

BILLING CODE 4310–70–M

DEPARTMENT OF JUSTICE

National Institute of Corrections

Advisory Board Meeting

TIME AND DATE: 8:00 a.m., Tuesday, November 18, 1997 (changed from October 21, 1997).

PLACE: Sheraton National Hotel, 900 South Orme Street, Arlington, VA 22204.

STATUS: Open.

MATTERS TO BE CONSIDERED: Updates on NIC's strategic planning; survey concerning civil commitment of sex offenders; interstate compact; victims' issues discussion points; amendment of the Bylaws; election of officers/liaisons; orientation for new Board members; and the Office of Justice Programs quarterly report.

CONTACT PERSON FOR MORE INFORMATION: Larry Solomon, Deputy Director. (202) 307–3106, ext. 155.

Morris L. Thigpen,

Director.

[FR Doc. 97–27599 Filed 10–16–97; 8:45 am]

BILLING CODE 4410–36–M

DEPARTMENT OF LABOR

Office of the Secretary

Bureau of International Labor Affairs; U.S. National Administrative Office; North American Agreement on Labor Cooperation; Hearing on Submission #9701

AGENCY: Office of the Secretary, Labor.

ACTION: Notice of hearing.

SUMMARY: The purpose of this notice is to announce a hearing, open to the public, on Submission #9701.

Submission #9701, filed with the U.S. National Administrative Office (NAO) by Human Rights Watch (HRW), the International Labor Rights Fund (ILRF), and the National Association of Democratic Lawyers (ANAD) of Mexico, involves labor law matters in Mexico and was accepted for review by the NAO on July 14, 1997. Notice of acceptance for review was published in the **Federal Register** on July 17, 1997 (62 FR 38327).

Article 16 (3) of the North American Agreement on Labor Cooperation (NAALC) provides for the review of labor law matters in Canada and Mexico by the NAO in accordance with U.S. domestic procedures. Revised procedural guidelines pertaining to the submission, review, and reporting process utilized by the Office were published in the **Federal Register** on April 7, 1994 (59 F.R. 16660). The guidelines provide for a discretionary hearing as part of the review.

DATES: The hearing will be held on November 19, 1997, commencing at 9:00 a.m. Persons desiring to present oral testimony at the hearing must submit a request in writing, along with a written statement or brief describing the information to be presented or position to be taken.

ADDRESSES: The hearing will be held in Brownsville, Texas, at the Brownsville Public Library located at 2600 Central Boulevard, Brownsville, Texas 78520, Main Meeting Room, Room #102. Written statements or briefs and requests to present oral testimony may be mailed or hand delivered to the U.S. National Administrative Office (NAO), Department of Labor, 200 Constitution Avenue, N.W., Room C–4327, Washington, D.C. 20210. Requests to present oral testimony and written statements or briefs must be received by the NAO no later than close of business, November 5, 1997.

FOR FURTHER INFORMATION CONTACT: Irasema T. Garza, Secretary, U.S. National Administrative Office, Department of Labor, 200 Constitution Avenue, N.W., Room C–4327, Washington, D.C. 20210. Telephone: (202) 501–6653 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION:

I. Nature and Conduct of Hearing

As set out in the notice published in the **Federal Register** on July 17, 1997, the objective of the NAO's review of the submission is to gather information to better understand and publicly report on the Government of Mexico's promotion of compliance with, and effective enforcement of, its labor law through appropriate government action, as set out in Article 3(1) of the NAALC, and on the steps the Government of Mexico has taken to ensure access to tribunals for the enforcement of labor law and recourse to procedures under which labor rights are protected in accordance with Articles 4(1) and 4(2) of the NAALC.

The hearing will be conducted by the Secretary of the NAO or the Secretary's designee. It will be open to the public. All proceedings will be conducted in English, with simultaneous translation in English and Spanish provided. The public files for the submission, including written statements, briefs, and requests to present oral testimony, will be made a part of the appropriate hearing record. The public files will also be available for inspection at the NAO prior to the hearing.

The hearing will be transcribed. A transcript of the proceeding will be made available for inspection, as provided for in Section E of the procedural guidelines, or may be purchased from the reporting company.

Disabled persons should contact the Secretary of the NAO no later than November 5, 1997, if special accommodations are needed.

II. Written Statements or Briefs and Requests To Present Oral Testimony

Written statements or briefs shall provide a description of the information to be presented or position taken and shall be legibly typed or printed. Requests to present oral testimony shall include the name, address, and telephone number of the witness, the organization represented, if any, and any other information pertinent to the request. Five copies of a statement or brief and a single copy of a request to present oral testimony shall be submitted to the NAO at the time of filing.

No request to present oral testimony will be considered unless accompanied by a written statement or brief. A request to present oral testimony may be denied if the written statement or brief suggests that the information sought to be provided is unrelated to the review of the submission or for other appropriate reasons. The NAO will notify each requester of the disposition of the request to present oral testimony.

In presenting testimony, the witness should summarize the written statement or brief, may supplement the written statement or brief with relevant information, and should be prepared to answer questions from the Secretary of the NAO or the Secretary's designee. Oral testimony will ordinarily be limited to a ten minute presentation, not including the time for questions. Persons desiring more than ten minutes for their presentation should so state in the request, setting out reasons why additional time is necessary.

The requirements relating to the submission of written statements or briefs and requests to present oral testimony may be waived by the Secretary of the NAO for reasons of equity and public interest.

Signed at Washington, D.C. on October 14, 1997.

Irasema T. Garza,

Secretary, U.S. National Administrative Office.

[FR Doc. 97–27592 Filed 10–16–97; 8:45 am]

BILLING CODE 4510–28–M

DEPARTMENT OF LABOR

Employment Standards Administration Wage and Hour Division

Minimum Wages for Federal and Federally Assisted Construction; General Wage Determination Decisions

General wage determination decisions of the Secretary of Labor are issued in accordance with applicable law and are based on the information obtained by the Department of Labor from its study of local wage conditions and data made available from other sources. They specify the basic hourly wage rates and fringe benefits which are determined to be prevailing for the description classes of laborers and mechanics employed on construction projects of a similar character and in the localities specified therein.

The determinations in these decisions of prevailing rates and fringe benefits have been made in accordance with 29 CFR Part 1, by authority of the Secretary of Labor pursuant to the provisions of the Davis-Bacon Act of March 3, 1931, as amended (46 Stat. 1494, as amended, 40 U.S.C. 276a) and the other Federal statues referred to in 29 CFR Part 1, Appendix, as well as such additional statutes as may from time to time be enacted containing provisions for the payment of wages determined to be prevailing by the Secretary of Labor in accordance with the Davis-Bacon Act. The prevailing rates and fringe benefits determined in these decisions shall, in accordance with the provisions of the foregoing statutes, constitute the minimum wages payable on Federal and federally assisted construction projects to laborers and mechanics of the specified classes engaged on contract work of the character and in the localities described therein.

Good cause is hereby found for not utilizing notice and public comment procedure thereon prior to the issuance of these determinations as prescribed in 5 U.S.C. 553 and not providing for delay in the effective date as prescribed in that section, because the necessity to issue current construction industry wage determinations frequently and in large volume causes procedures to be impractical and contrary to the public interest.

General wage determination decisions, and modifications and supersedes decisions thereto, contain no expiration dates and are effective from their date of notice in the **Federal Register**, or on the date written notice is received by the agency, whichever is earlier. These decisions are to be used in accordance with the provisions of 29 CFR Parts 1 and 5. Accordingly, the applicable decision, together with any modifications issued, must be made a part of every contract for performance of the described work within the geographic area indicated as required by an applicable Federal prevailing wage law and 29 CFR Part 5. The wage rates and fringe benefits, notice of which is published herein, and which are contained in the Government Printing Office (GPO) document entitled ''General Wage Determinations Issued Under The Davis-Bacon And Related Acts,'' shall be the minimum paid by contractors and subcontractors to laborers and mechanics.

Any person, organization, or governmental agency having an interest in the rates determined as prevailing is encouraged to submit wage rate and fringe benefit information for consideration by the Department. Further information and self-explanatory forms for the purpose of submitting this data may be obtained by writing to the U.S. Department of Labor, Employment Standards Administration, Wage and Hour Division, Division of Wage Determinations, 200 Constitution Avenue, N.W., Room S–3014, Washington, D.C. 20210.

New General Wage Determination Decisions

The number of the decisions added to the Government Printing Office document entitled ''General Wage Determinations Issued Under the Davis-Bacon and related Acts'' are listed by Volume and States:

Volume IV:

Michigan
- MI970082 (Oct. 17, 1997)
- MI970083 (Oct. 17, 1997)
- MI970084 (Oct. 17, 1997)
- MI970085 (Oct. 17, 1997)
- MI970086 (Oct. 17, 1997)

Ohio
- OH970036 (Oct. 17, 1997)
- OH970037 (Oct. 17, 1997)

Modificaitons to General Wage Determination Decisions

The number of decisions listed in the Government Printing Office document entitled ''General Wage Determinations Issued Under the Davis-Bacon and Related Acts.'' being modified are listed by Volume and State. Dates of publication in the **Federal Register** are in parentheses following the decisions being modified.

Volume I:

Maine
- ME970005 (Feb. 14, 1997)
- ME970007 (Feb. 14, 1997)
- ME970010 (Feb. 14, 1997)
- ME970022 (Feb. 14, 1997)
- ME970037 (Feb. 14, 1997)

Rhode Island
- RI970001 (Feb. 14, 1997)

Volume II:

Delaware
- DE970001 (Feb. 14, 1997)
- DE970002 (Feb. 14, 1997)
- DE970004 (Feb. 14, 1997)
- DE970005 (Feb. 14, 1997)
- DE970009 (Feb. 14, 1997)

Maryland
- MD970001 (Feb. 14, 1997)
- MD970021 (Feb. 14, 1997)
- MD970034 (Feb. 14, 1997)
- MD970036 (Feb. 14, 1997)
- MD979937 (Feb. 14, 1997)
- MD970042 (Feb. 14, 1997)
- MD970057 (Feb. 14, 1997)
- MD970058 (Feb. 14, 1997)

Pennsylvania
- PA970001 (Feb. 14, 1997)
- PA970002 (Feb. 14, 1997)
- PA970004 (Feb. 14, 1997)
- PA970005 (Feb. 14, 1997)
- PA970006 (Feb. 14, 1997)
- PA970017 (Feb. 14, 1997)
- PA970018 (Feb. 14, 1997)
- PA970020 (Feb. 14, 1997)
- PA970026 (Feb. 14, 1997)
- PA970032 (Feb. 14, 1997)
- PA970033 (Feb. 14, 1997)
- PA970038 (Feb. 14, 1997)
- PA970042 (Feb. 14, 1997)
- PA970051 (Feb. 14, 1997)
- PA970053 (Feb. 14, 1997)
- PA970065 (Feb. 14, 1997)

Virginia
- VA970025 (Feb. 14, 1997)
- VA970052 (Feb. 14, 1997)
- VA970078 (Feb. 14, 1997)
- VA970079 (Feb. 14, 1997)

Volume III:

Florida
- FL970039 (Feb. 14, 1997)

Kentucky
- KY970001 (Feb. 14, 1997)
- KY970002 (Feb. 14, 1997)
- KY970003 (Feb. 14, 1997)
- KY970004 (Feb. 14, 1997)
- KY970006 (Feb. 14, 1997)
- KY970007 (Feb. 14, 1997)
- KY970025 (Feb. 14, 1997)
- KY970027 (Feb. 14, 1997)
- KY970029 (Feb. 14, 1997)
- KY970032 (Feb. 14, 1997)
- KY970035 (Feb. 14, 1997)
- KY970054 (Feb. 14, 1997)

Tennessee
- TN970002 (Feb. 14, 1997)
- TN970005 (Feb. 14, 1997)
- TN970018 (Feb. 14, 1997)
- TN970038 (Feb. 14, 1997)
- TN970039 (Feb. 14, 1997)

Volume IV:

Indiana
IN970004 (Feb. 14, 1997)
IN970006 (Feb. 14, 1997)
IN970017 (Feb. 14, 1997)
IN970020 (Feb. 14, 1997)
Michigan
MI970001 (Feb. 14, 1997)
MI970003 (Feb. 14, 1997)
MI970004 (Feb. 14, 1997)
MI970007 (Feb. 14, 1997)
MI970017 (Feb. 14, 1997)
MI970030 (Feb. 14, 1997)
MI970031 (Feb. 14, 1997)
MI970046 (Feb. 14, 1997)
MI970047 (Feb. 14, 1997)
MI970078 (Feb. 14, 1997)
MI970079 (Feb. 14, 1997)
MI970080 (Feb. 14, 1997)
Minnesota
MN970007 (Feb. 14, 1997)
MN970008 (Feb. 14, 1997)
MN970015 (Feb. 14, 1997)
MN970027 (Feb. 14, 1997)
MN970031 (Feb. 14, 1997)
MN970035 (Feb. 14, 1997)
MN970039 (Feb. 14, 1997)
MN970061 (Feb. 14, 1997)
Ohio
OH970001 (Feb. 14, 1997)
OH970002 (Feb. 14, 1997)
OH970003 (Feb. 14, 1997)
OH970009 (Feb. 14, 1997)
OH970012 (Feb. 14, 1997)
OH970026 (Feb. 14, 1997)
OH970028 (Feb. 14, 1997)
OH970029 (Feb. 14, 1997)
OH970035 (Feb. 14, 1997)

Volume V

Arkansas
AR970003 (Feb. 14, 1997)
Iowa
IA970013 (Feb. 14, 1997)
Kansas
KS970006 (Feb. 14, 1997)
Missouri
MO970001 (Feb. 14, 1997)
MO970002 (Feb. 14, 1997)
MO970006 (Feb. 14, 1997)
MO970009 (Feb. 14, 1997)
MO970011 (Feb. 14, 1997)
MO970013 (Feb. 14, 1997)
MO970041 (Feb. 14, 1997)
MO970042 (Feb. 14, 1997)
MO970050 (Feb. 14, 1997)
MO970058 (Feb. 14, 1997)
MO970067 (Feb. 14, 1997)
MO970072 (Feb. 14, 1997)
Texas
TX970018 (Feb. 14, 1997)
TX970114 (Feb. 14, 1997)

Volume VI:

Idaho
ID970001 (Feb. 14, 1997)
ID970002 (Feb. 14, 1997)
Oregon
OR970001 (Feb. 14, 1997)
OR970017 (Feb. 14, 1997)
Washington
WA970005 (Feb. 14, 1997)

Volume VII:

California
CA970001 (Feb. 14, 1997)
CA970002 (Feb. 14, 1997)
CA970028 (Feb. 14, 1997)
CA970029 (Feb. 14, 1997)
CA970030 (Feb. 14, 1997)
CA970031 (Feb. 14, 1997)
CA970032 (Feb. 14, 1997)
CA970033 (Feb. 14, 1997)
CA970034 (Feb. 14, 1997)
CA970035 (Feb. 14, 1997)
CA970036 (Feb. 14, 1997)
CA970037 (Feb. 14, 1997)
CA970038 (Feb. 14, 1997)
CA970039 (Feb. 14, 1997)
CA970040 (Feb. 14, 1997)
CA970041 (Feb. 14, 1997)
CA970042 (Feb. 14, 1997)
CA970043 (Feb. 14, 1997)
CA970044 (Feb. 14, 1997)
CA970045 (Feb. 14, 1997)
CA970046 (Feb. 14, 1997)
CA970047 (Feb. 14, 1997)
CA970048 (Feb. 14, 1997)

General Wage Determination Publication

General wage determinations issued under the Davis-Bacon and related Acts, including those noted above, may be found in the Government Printing Office (GPO) document entitled ''General Wage Determinations Issued Under The Davis-Bacon and Related Acts''. This publication is available at each of the 50 Regional Government Depository Libraries and many of the 1,400 Government Depository Libraries across the county.

The general wage determinations issued under the Davis-Bacon and related Acts are available electronically by subscription to the FedWorld Bulletin Board System of the National Technical Information Service (NTIS) of the U.S. Department of Commerce at (703) 487–4630.

Hard-copy subscriptions may be purchased from: Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402, (202) 512–1800.

When ordering hard-copy subscription(s), be sure to specify the State(s) of interest, since subscriptions may be ordered for any or all of the seven separate volumes, arranged by State. Subscriptions include an annual edition (issued in January or February) which includes all current general wage determinations for the States covered by each volume. Throughout the remainder of the year, regular weekly updates are distributed to subscribers.

Signed at Washington, D.C. This 10th day of October 1997.

Margaret Washington,

Acting Chief, Branch of Construction Wage Determinations.

[FR Doc. 97–27415 Filed 10–16–97; 8:45 am]

BILLING CODE 4510–27–M

NUCLEAR REGULATORY COMMISSION

Advisory Committee on Reactor Safeguards; Meeting Notice

In accordance with the purposes of Sections 29 and 182b. of the Atomic Energy Act (42 U.S.C. 2039, 2232b), the Advisory Committee on Reactor Safeguards will hold a meeting on November 6–7, 1997, in Conference Room T–2B3, 11545 Rockville Pike, Rockville, Maryland. The date of this meeting was previously published in the **Federal Register** on Thursday, January 23, 1997 (62 FR 3539).

Thursday, November 6, 1997

8:30 A.M.—8:45 A.M.: Opening Remarks by the ACRS Chairman (Open)—The ACRS Chairman will make opening remarks regarding conduct of the meeting and comment briefly regarding items of current interest. During this session, the Committee will discuss priorities for preparation of ACRS reports.

8:45 A.M.—10:15 A.M.: Use of Uncertainty Versus Point Values in the PRA-Related Decisionmaking Process (Open)—The Committee will hear presentations by and hold discussions with representatives of the NRC staff regarding the adequacy of the guidance being provided by the staff relative to the use of uncertainty versus point values in the PRA-related decisionmaking process.

10:30 A.M.—12:00 Noon: Proposed Final Generic Letter Regarding Loss of Reactor Coolant Inventory and Associated Potential for loss of Emergency Mitigation Functions While in a Shutdown Condition (Open)—The Committee will hear presentations by and hold discussions with representatives of the NRC staff regarding the proposed final Generic Letter noted above.

1:00 P.M.—2:30 P.M.: Meeting with the Acting Deputy Executive Director for Regulatory Effectiveness (Open)—The Committee will hear presentations by and hold discussions with the Acting Deputy Executive Director regarding regulatory excellence and related matters.

2:45 P.M.—4:15 P.M.: NRC Safety Research Program (Open)—The Committee will hear presentations by and hold discussions with the staff, as needed, regarding the NRC Safety Research Program and related matters.

4:30 P.M.—7:00 P.M.: Preparation of ACRS Reports (Open)—The Committee will discuss proposed ACRS reports on matters considered during this meeting.

Friday, November 7, 1997

8:30 A.M.—8:35 A.M.: Opening Remarks by the ACRS Chairman (Open)—The ACRS Chairman will make opening remarks regarding conduct of the meeting.

8:35 A.M.—9:35 A.M.: Severe Accident Management (Open)—The Committee will hear presentations by and hold discussions with representatives of the NRC staff regarding the staff evaluation of the BWR Owners Group emergency procedure and severe accident guidelines and the Westinghouse severe accident guidelines.

9:35 A.M.—10:30 A.M.: Staff Actions Related to the Development of a Revised Fire Protection Rule (Open)—The Committee will hear presentations by and hold discussions with representatives of the NRC staff regarding staff actions related to the development of a revised Fire Protection Rule.

10:45 A.M.—11:15 A.M.: Future ACRS Activities (Open)—The Committee will discuss the recommendations of the Planning and Procedures Sub-committee regarding items proposed for consideration by the full Committee during future meetings.

11:15 A.M.—11:30 A.M.: Reconciliation of ACRS Comments and Recommendations (Open)—The Committee will discuss responses from the NRC Executive Director for Operations to comments and recommendations included in recent ACRS reports. The EDO responses are expected to be provided to the ACRS prior to the meeting.

11:30 A.M.—12:00 Noon: Report of the Planning and Procedures Subcommittee (Open/Closed)—The Committee will hear a report of the Planning and Procedures Subcommittee on matters related to the conduct of ACRS business, qualifications of candidates nominated for appointment to the ACRS, and organizational and personnel matters relating to the ACRS.

[Note: A portion of this session may be closed to discuss organizational and personnel matters that relate solely to the internal personnel rules and practices of this Advisory Committee, and information the release of which would constitute a clearly unwarranted invasion of personal privacy.]

1:00 P.M.—1:30 P.M.: Miscellaneous (Open)—The Committee will discuss matters related to the conduct of Committee activities and matters and specific issues that were not completed during previous meetings, as time and availability of information permit.

1:30 P.M.—7:00 P.M.: Preparation of ACRS Reports (Open)—The Committee will continue its discussion regarding proposed ACRS reports on matters considered during this meeting.

Procedures for the conduct of and participation in ACRS meetings were published in the **Federal Register** on September 4, 1997 (62 FR 46782). In accordance with these procedures, oral or written statements may be presented by members of the public and representatives of the nuclear industry, electronic recordings will be permitted only during the open portions of the meeting, and questions may be asked only by members of the Committee, its consultants, and staff. Persons desiring to make oral statements should notify Mr. Sam Duraiswamy, Chief, Nuclear Reactors Branch, at least five days before the meeting, if possible, so that appropriate arrangements can be made to allow the necessary time during the meeting for such statements. Use of still, motion picture, and television cameras during this meeting may be limited to selected portions of the meeting as determined by the Chairman. Information regarding the time to be set aside for this purpose may be obtained by contacting the Chief of the Nuclear Reactors Branch prior to the meeting. In view of the possibility that the schedule for ACRS meetings may be adjusted by the Chairman as necessary to facilitate the conduct of the meeting, persons planning to attend should check with the Chief of the Nuclear Reactors Branch if such rescheduling would result in major inconvenience.

In accordance with Subsection 10(d) P.L. 92–463, I have determined that it is necessary to close portions of this meeting noted above to discuss matters that relate solely to the internal personnel rules and practices of this Advisory Committee per 5 U.S.C. 552b(c)(2), and to discuss information the release of which would constitute a clearly unwarranted invasion of personal privacy per 5 U.S.C. 552b(c)(6).

Further information regarding topics to be discussed, whether the meeting has been cancelled or rescheduled, the Chairman's ruling on requests for the opportunity to present oral statements and the time allotted therefor, can be obtained by contacting Mr. Sam Duraiswamy, Chief, Nuclear Reactors Branch (telephone 301/415–7364), between 7:30 A.M. and 4:15 P.M. EDT.

ACRS meeting notices, meeting transcripts, and letter reports are now available on FedWorld from the ''NRC MAIN MENU.'' The Direct Dial Access number to FedWorld is (800) 303–9672 or ftp.fedworld. These documents and the meeting agenda are also available for downloading or reviewing on the internet at http://www.nrc.gov/ACRSACNW.

Dated: October 10, 1997.

Andrew L. Bates,

Advisory Committee Management Officer.

[FR Doc. 97–27598 Filed 10–16–97; 8:45 am]

BILLING CODE 7590–01–P

OFFICE OF MANAGEMENT AND BUDGET

Cost of Hospital and Medical Care Treatment Furnished by the United States; Certain Rates Regarding Recovery From Tortiously Liable Third Persons

By virtue of the authority vested in the President by section 2(a) of Pub. L. 87–693 (76 Stat. 593; 42 U.S.C. 2652), and delegated to the Director of the Office of Management and Budget by Executive Order No. 11541 of July 1, 1970 (35 FR 10737), the three sets of rates outlined below are hereby established. These rates are for use in connection with the recovery, from tortiously liable third persons, of the cost of hospital and medical care and treatment furnished by the United States (Part 43, Chapter I, Title 28, Code of Federal Regulations) through three separate Federal agencies. The rates have been established in accordance with the requirements of OMB Circular A–25, requiring reimbursement of the full cost of all services provided. The rates are established as follows:

1. Department of Defense

The Fiscal Year 1998 (FY98) Department of Defense (DoD) reimbursement rates for inpatient, outpatient, and other services are provided in accordance with Section 1095 of title 10, United States Code. Due to size, the sections containing the Drug Reimbursement Rates (Section III.D) and the rates for Ancillary Services Requested by Outside Providers (Section III.E) are not included in this package. The Office of the Assistant Secretary of Defense (Health Affairs) will provide these rates upon request. The medical and dental service rates in this package (including the rates for ancillary services, prescription drugs or other procedures requested by outside providers) are effective October 1, 1997.

2. Health and Human Services

The sum of obligations for each cost center providing medical service is broken down into amounts attributable to inpatient care on the basis of the proportion of staff devoted to each cost center. Total inpatient costs and outpatient costs thus determined are

divided by the relevant workload statistic (inpatient day, outpatient visit) to produce the inpatient and outpatient rates. In calculation of the rates, the Department's unfunded retirement liability cost and capital and equipment depreciation cost were incorporated to conform to requirements set forth in OMB Circular A–25. In addition, each cost center's obligations include costs for certain other accounts, such as Medicare and Medicaid collections and Contract Health funds used to support direct program operation. Certain cost centers that primarily support workload outside of the directly operated hospitals or clinics (public health nursing, public health nutrition, health education) were excluded this year as not being a part of the traditional cost of hospital operations and not contributing directly to the inpatient and outpatient visit workload. Overall, these rates reflect a more accurate indication of the cost of care in HHS facilities.

In addition, separate rates per inpatient day and outpatient visit were computed for Alaska and the rest of the United States. This gives proper weight to the higher cost of operating medical facilities in Alaska.

3. Department of Veterans Affairs

Actual direct and indirect costs are compiled by type of care for the previous year, and facility overhead costs are added. Adjustments are made using the budgeted percentage changes for the current year and the budget year to compute the base rate for the budget year. The budget year base rate is then adjusted by estimated costs for depreciation of buildings and equipment, central office overhead, Government employee retirement benefits, and return on fixed assets (interest on capital for land, buildings, and equipment (net book value)), to compute the budget year tortiously liable reimbursement rates. Also shown for the tortiously liable inpatient per diem rates are breakdowns into three cost components: Physician; Ancillary; and Nursing, Room, and Board. As with the total per diem rates, these breakdowns are calculated from actual data by type of care.

The interagency rates shown are to be used when VA medical care or service is furnished to a beneficiary of another Federal agency, and that care or service is not covered by an applicable local sharing agreement. Government employee retirement benefits and return on fixed assets are not included in the interagency rates, but in all other respects the interagency rates are the same as the tortiously liable rates.

Inpatient charges will be at the per diem rates shown for the type of bed section or discrete treatment unit providing the care. Prescription Filled charge in lieu of the Outpatient Visit rate will be charged when the patient receives no service other than the Pharmacy outpatient service. This charge applies whether the patient receives the prescription in person or by mail.

When medical care or service is obtained at the expense of the Department of Veterans Affairs from a non-VA source, the charge for such care or service will be the actual amount paid by the VA for that care or service.

1. Department of Defense

For the Department of Defense, effective October 1, 1997 and thereafter:

Inpatient, Outpatient and Other Rates and Charges

I. Inpatient Rates [1 2]

Per inpatient day	International Military Education & Training (IMET)	Interagency and other Federal agency sponsored patients	Other (Full/Third party)
A. Burn Center	$2,618.00	$4,754.00	$5,079.00
B. Surgical Care Services (Cosmetic Surgery)	955.00	1,733.00	1852.00
C. All Other Inpatient Services (Based on Diagnosis Related Groups (DRG) [3])			

1. FY98 Direct Care Inpatient Reimbursement Rates

Adjusted standard amount	IMET	Other interagency	(Full/Third party)
Large Urban	$2,199.00	$4,131.00	$4,372.00
Other Urban/Rural	2,194.00	4,215.00	4,499.00
Overseas	2,450.00	5,614.00	5,960.00

2. Overview

The FY98 inpatient rates are based on the cost per DRG, which is the inpatient full reimbursement rate per hospital discharge weighted to reflect the intensity of the principal diagnosis, secondary diagnoses, procedures, patient age, etc. involved. The average cost per Relative Weighted Product (RWP) for large urban, other urban/rural, and overseas facilities will be published annually as an inpatient adjusted standardized amount (ASA) (see paragraph I.C.1., above). The ASA will be applied to the RWP for each inpatient case, determined from the DRG weights, outlier thresholds, and payment rules published annually for hospital reimbursement rates under the Civilian Health and Medical Program of the Uniformed Services (CHAMPUS) pursuant to 32 CFR 199.14(a)(1), including adjustments for length of stay (LOS) outliers. The published ASAs will be adjusted for area wage differences and indirect medical education (IME) for the discharging hospital. An example of how to apply DoD costs to a DRG standardized weight to arrive at DoD costs is contained in paragraph I.C.3., below.

3. Example of Adjusted Standardized Amounts for Inpatient Stays

Figure 1 shows examples for a nonteaching hospital in a Large Urban Area.

a. The cost to be recovered is DoD's cost for medical services provided in the nonteaching hospital located in a large urban area. Billings will be at the third party rate.

b. DRG 020: Nervous System Infection Except Viral Meningitis. The RWP for an inlier case is the CHAMPUS weight of 2.9769. (DRG statistics shown are from FY 1996).

c. The DoD adjusted standardized amount to be charged is $4,372 (i.e., the third party rate as shown in the table).

d. DoD cost to be recovered at a nonteaching hospital with area wage index of 1.0 is the RWP factor (2.9769) in 3.b., above, multiplied by the amount ($4,372) in 3.c., above.

e. Cost to be recovered is $13,015.

FIGURE 1.—THIRD PARTY BILLING EXAMPLES

DRG No.	DRG description	DRG weight	Arithmetic mean LOS	Geometric mean LOS	Short stay threshold	Long stay threshold
020 ...	Nervous System Infection Except Viral Meningitis	2.9769	11.2	7.8	1	30

Hospital	Location	Area wage rate index	IME adjustment	Group ASA	Applied ASA
Nonteaching Hospital	Large Urban	1.0	1.0	$4,372.00	$4,372.00

Patient	Length of stay	Days above threshold	Relative weighted product			TPC
			Inlier*	Outlier**	Total	Amount***
#1	7 days	0	2.9769	0.0000	2.9769	$13,015
#2	21 days	0	2.9769	0.0000	2.9769	13,015
#3	35 days	5	2.9769	0.6297	3.6066	15,768

*DRG Weight

**Outlier calculation = 33 percent of per diem weight′ number of outlier days = .33 (DRG Weight/Geometric Mean LOS)′ (Patient LOS—Long Stay Threshold)

=.33 (2.9769/7.8) ′ (35–30)

=.33 (.38165)′ 5 (take out to five decimal places)

=.12594′ 5 (take out to five decimal places)

=.6297 (take out to four decimal places)

*** Applied ASA′ Total RWP

II. Outpatient Rates [1] [2] Per Visit

MEPRS Code [4]	Clinical service	International Military Education & Training (IMET)	Interagency and other Federal agency sponsored patients	Other (Full/Third party)
	A. Medical Care			
BAA	Internal Medicine	$105.00	$195.00	$208.00
BAB	Allergy	39.00	73.00	78.00
BAC	Cardiology	81.00	150.00	160.00
BAE	Diabetic	44.00	82.00	87.00
BAF	Endocrinology (Metabolism)	85.00	158.00	168.00
BAG	Gastroenterology	110.00	203.00	216.00
BAH	Hematology	145.00	269.00	287.00
BAI	Hypertension	81.00	149.00	159.00
BAJ	Nephrology	171.00	317.00	338.00
BAK	Neurology	109.00	202.00	215.00
BAL	Outpatient Nutrition	34.00	63.00	67.00
BAM	Oncology	114.00	211.00	225.00
BAN	Pulmonary Disease	141.00	260.00	278.00
BAO	Rheumatology	84.00	156.00	166.00
BAP	Dermatology	63.00	117.00	124.00
BAQ	Infectious Disease	141.00	260.00	278.00
BAR	Physical Medicine	78.00	145.00	155.00
BAS	Radiation Therapy	72.00	132.00	141.00
BAZ	Medical Care Not Elsewhere Classified (NEC)	84.00	156.00	166.00
	B. Surgical Care			
BBA	General Surgery	119.00	220.00	235.00
BBB	Cardiovascular and Thoracic Surgery	110.00	203.00	216.00
BBC	Neurosurgery	137.00	253.00	270.00
BBD	Ophthalmology	84.00	155.00	166.00
BBE	Organ Transplant	191.00	353.00	376.00
BBF	Otolaryngology	88.00	162.00	173.00
BBG	Plastic Surgery	100.00	184.00	196.00
BBH	Proctology	67.00	124.00	132.00

MEPRS Code [4]	Clinical service	International Military Education & Training (IMET)	Interagency and other Federal agency sponsored patients	Other (Full/Third party)
BBI	Urology	101.00	187.00	199.00
BBJ	Pediatric Surgery	89.00	164.00	175.00
BBZ	Surgical Care NEC	65.00	120.00	127.00
	C. Obstetrical and Gynecological (OB–GYN) Care			
BCA	Family Planning	45.00	83.00	89.00
BCB	Gynecology	74.00	136.00	146.00
BCC	Obstetrics	68.00	126.00	135.00
BCZ	OB-GYN Care NEC	112.00	207.00	221.00D
	D. Pediatric Care			
BDA	Pediatric	54.00	100.00	106.00
BDB	Adolescent	55.00	101.00	108.00
BDC	Well Baby	36.00	66.00	70.00
BDZ	Pediatric Care NEC	64.00	119.00	126.00
	E. Orthopaedic Care			
BEA	Orthopaedic	83.00	153.00	164.00
BEB	Cast	45.00	82.00	88.00
BEC	Hand Surgery	38.00	70.00	75.00
BEE	Orthotic Laboratory	59.00	110.00	117.00
BEF	Podiatry	49.00	91.00	97.00
BEZ	Chiropractic	21.00	38.00	40.00
	F. Psychiatric and/or Mental Health Care			
BFA	Psychiatry	97.00	179.00	191.00
BFB	Psychology	71.00	132.00	141.00
BFC	Child Guidance	59.00	109.00	117.00
BFD	Mental Health	80.00	147.00	157.00
BFE	Social Work	80.00	149.00	159.00
BFF	Substance Abuse	62.00	115.00	123.00
	G. Family Practice/Primary Medical Care			
BGA	Family Practice	67.00	124.00	132.00
BHA	Primary Care	64.00	118.00	126.00
BHB	Medical Examination	59.00	109.00	117.00
BHC	Optometry	42.00	77.00	82.00
BHD	Audiology	30.00	55.00	58.00
BHE	Speech Pathology	81.00	149.00	159.00
BHF	Community Health	41.00	75.00	80.00
BHG	Occupational Health	59.00	108.00	115.00
BHH	TRICARE Outpatient	42.00	78.00	83.00
BHI	Immediate Care	82.00	152.00	162.00
BHZ	Primary Care NEC	43.00	79.00	84.00
	H. Emergency Medical Care			
BIA	Emergency Medical	107.00	198.00	211.00
	I. Flight Medical Care			
BJA	Flight Medicine	85.00	157.00	167.00
	J. Underseas Medical Care			
BKA	Underseas Medicine	32.00	58.00	62.00
	K. Rehabilitative Services			
BLA	Physical Therapy	29.00	54.00	57.00
BLB	Occupational Therapy	53.00	98.00	104.00

III. Other Rates and Charges [1] [2] Per Visit

MEPRS code [4]	Clinical service	International Military Education & Training (IMET)	Interagency and other Federal agency sponsored patients	Other (Full/Third party)
FBI	A. Immunization	$10.00	$19.00	$20.00
DGC	B. Hyperbaric Chamber [5]	180.00	333.00	355.00
	C. Ambulatory Procedure Visit (APV) [6]	376.00	691.00	737.00
	D. Family Member Rate (formerly Military Dependents Rate)	10.20		

E. Reimbursement Rates For Drugs Requested By Outside Providers [7]

The FY98 drug reimbursement rates for drugs are for prescriptions requested by outside providers and obtained at a Military Treatment Facility. The rates are established based on the cost of the particular drugs provided. Final rule of 32 CFR part 220, estimated to be published October 1, 1997, will eliminate the high cost ancillary services' dollar threshold and the associated term ''high cost ancillary service.'' In anticipation of that change, the phrase ''high cost ancillary service'' has been replaced with the phrase ''ancillary services requested by an outside provider.'' The list of drug reimbursement rates is too large to include here. These rates are available on request from OASD (Health Affairs)—see Tab N for the point of contact.

F. Reimbursement Rates for Ancillary Services Requested By Outside Providers [8]

Final rule of 32 CFR part 220, estimated to be published October 1, 1997, will eliminate the high cost ancillary services' dollar threshold and the associated term ''high cost ancillary service.'' In anticipation of that change, the phrase ''high cost ancillary service'' has been replaced with the phrase ''ancillary services requested by an outside provider.'' The list of FY98 rates for ancillary services requested by outside providers and obtained at a Military Treatment Facility is too large to include here. These rates are available on request from OASD(Health Affairs)—see Tab N for the point of contact.

G. Elective Cosmetic Surgery Procedures and Rates

Cosmetic surgery procedure	International Classification Diseases (ICD–9)	Current Procedural Terminology (CPT) [9]	FY98 charge [10]	Amount of charge
Mammaplasty	85.50, 85.32, 85.31	19325, 19324, 19318	Inpatient Surgical Care Per Diem or APV or applicable Outpatient Clinic Rate.	(a b c)
Mastopexy	85.60	19316	Inpatient Surgical Care Per Diem or APV or applicable Outpatient Clinic Rate.	(a b c)
Facial Rhytidectomy	86.82, 86.22	15824	Inpatient Surgical Care Per Diem or APV or applicable Outpatient Clinic Rate.	(a b c)
Blepharoplasty	08.70, 08.44	15820, 15821, 15822, 15823.	Inpatient Surgical Care Per Diem or APV or applicable Outpatient Clinic Rate.	(a b c)
Mentoplasty (Augmentation Reduction).	76.68, 76.67	21208, 21209	Inpatient Surgical Care Per Diem or APV or applicable Outpatient Clinic Rate.	(a b c)
Abdominoplasty	86.83	15831	Inpatient Surgical Care Per Diem or APV or applicable Outpatient Clinic Rate.	(a b c)
Lipectomy suction per region [11].	86.83	15876, 15877, 15878, 15879.	Inpatient Surgical Care Per Diem or APV or applicable Outpatient Clinic Rate.	(a b c)
Rhinoplasty	21.87, 21.86	30400, 30410	Inpatient Surgical Care Per Diem or APV or applicable Outpatient Clinic Rate.	(a b c)
Scar Revisions beyond CHAMPUS.	86.84	1578__	Inpatient Surgical Care Per Diem or APV or applicable Outpatient Clinic Rate.	(a b c)
Mandibular or Maxillary Repositioning.	76.41	21194	Inpatient Surgical Care Per Diem or APV or applicable Outpatient Clinic Rate.	(a b c)
Minor Skin Lesions [12]	86.30	1578__	Inpatient Surgical Care Per Diem or APV or applicable Outpatient Clinic Rate.	(a b c)
Dermabrasion	86.25	15780	Inpatient Surgical Care Per Diem or APV or applicable Outpatient Clinic Rate.	(a b c)
Hair Restoration	86.64	15775	Inpatient Surgical Care Per Diem or APV or applicable Outpatient Clinic Rate.	(a b c)
Removing Tattoos	86.25	15780	Inpatient Surgical Care Per Diem or APV or applicable Outpatient Clinic Rate.	(a b c)
Chemical Peel	86.24	15790	Inpatient Surgical Care Per Diem or APV or applicable Outpatient Clinic Rate.	(a b c)
Arm/Thigh Dermolipectomy.	86.83	1583__	Inpatient Surgical Care Per Diem or APV or applicable Outpatient Clinic Rate.	(a b c)
Brow Lift	86.3	15839	Inpatient Surgical Care Per Diem or APV or applicable Outpatient Clinic Rate.	(a b c)

H. Dental Rate [13] Per Procedure

MEPRS code [4]	Clinical service	International military education and training (IMET)	Interagency and other federal agency sponsored patients	Other (Full/third party)
	oDental Services ..... ADA code and DoD established weight.	$35.00	$101.00	$106.00

I. Ambulance Rate [14] Per Visit

MEPRS code [4]	Clinical service	International military education and training (IMET)	nteragency and other federal agency sponsored patients	Other (Full/Third party)
FEA	Ambulance	$32.00	$60.00	$64.00

J. Laboratory and Radiology Services Requested by an Outside Provider [8] Per Procedure

MEPRS code [4]	Clinical service	International military education & training (IMET)	nteragency & other federal agency sponsored patients	Other (full/third party)
	Laboratory procedures requested by an outside provider CPT–4 Weight Multiplier.	$9.00	$13.00	$14.00
	Radiology procedures requested by an outside provider CPT–4 Weight Multiplier.	23.00	35.00	37.00

K. AirEvac Rate [15] Per Visit

MEPRS code [4]	Clinical service	International military education and training (IMET)	Interagency and other federal agency sponsored patients	Other (Full/third party)
	AirEvac Services—Ambulatory	$113.00	$209.00	$223.00
	AirEvac Services—Litter	323.00	598.00	638.00

Notes on Cosmetic Surgery Charges

[a] Per diem charges for inpatient surgical care services are listed in section I.B. (See notes 9 through 11, below, for further details on reimbursable rates.)

[b] Charges for ambulatory procedure visits (formerly same day surgery) are listed in section III.C. (See notes 9 through 11, below, for further details on reimbursable rates.) The APV rate is used if the elective cosmetic surgery is performed in an ambulatory procedure unit (APU).

[c] Charges for outpatient clinic visits are listed in section II.A–K. The outpatient clinic rate is not used for services provided in an APU. The APV rate should be used in these cases.

Notes on Reimbursable Rates

[1] Percentages can be applied when preparing bills for both inpatient and outpatient services. Pursuant to the provisions of 10 U.S.C. 1095, the inpatient Diagnosis Related Groups and inpatient per diem percentages are 96 percent hospital and 4 percent professional charges. The outpatient per visit percentages are 88 percent outpatient services and 12 percent professional charges.

[2] DoD civilian employees located in overseas areas shall be rendered a bill when services are performed. Payment is due 60 days from the date of the bill.

[3] The cost per DRG (Diagnosis Related Group) is based on the inpatient full reimbursement rate per hospital discharge, weighted to reflect the intensity of the principal and secondary diagnoses, surgical procedures, and patient demographics involved. The adjusted standardized amounts (ASA) per Relative Weighted Product (RWP) for use in the direct care system is comparable to procedures used by the Health Care Financing Administration (HCFA) and the Civilian Health and Medical Program for the Uniformed Services (CHAMPUS). These expenses include all direct care expenses associated with direct patient care. The average cost per RWP for large urban, other urban/rural, and overseas will be published annually as an adjusted standardized amount (ASA) and will include the cost of inpatient professional services. The DRG rates will apply to reimbursement from all sources, not just third party payers.

[4] The Medical Expense and Performance Reporting System (MEPRS) code is a three digit code which defines the summary account and the subaccount within a functional category in the DoD medical system. MEPRS codes are used to ensure that consistent expense and operating performance data is reported in the DoD military medical system. An example of the MEPRS hierarchical arrangement follows: Outpatient Care (Functional Category), B (MEPRS Code), Medical Care (Summary Account), BA (MEPRS Code), Internal Medicine (Subaccount), BAA (MEPRS Code).

[5] Hyperbaric services charges shall be based on hours of service in 15 minute increments. The rates listed in section III.B. are for 60 minutes or 1 hour of service. Providers shall calculate the charges based on the number of hours (and/or fractions of an hour) of service. Fractions of an hour shall be rounded to the next 15 minute increment (e.g., 31 minutes shall be charged as 45 minutes).

[6] Ambulatory Procedure Visit (APV) is defined in DOD Instruction 6025.8, September 23, 1996, as immediate (day of procedure) pre-procedure and immediate post-procedure care requiring an unusual degree of intensity and provided in an ambulatory procedure

unit (APU). Care is required in the facility for less than 24 hours. This rate is also used for elective cosmetic surgery performed in an APU.

[7] Prescription services requested by outside providers (physicians, dentists, etc.) are relevant to the Third Party Collection Program. Third party payers (such as insurance companies) shall be billed for prescription services when beneficiaries who have medical insurance obtain medications from a Military Treatment Facility (MTF) that are prescribed by providers external to the MTF. Eligible beneficiaries (family members or retirees with medical insurance) are not personally liable for this cost and shall not be billed by the MTF. Medical Services Account (MSA) patients, who are not beneficiaries as defined in 10 U.S.C. 1074 and 1076, are charged at the ''Other'' rate if they are seen by an outside provider and come to the MTF for prescription services. The standard cost of medications ordered by an outside provider includes the cost of the drugs plus a dispensing fee per prescription. The prescription cost is calculated by multiplying the number of units (tablets, capsules, etc.) by the unit cost and adding a $5.00 dispensing fee per prescription. Final rule of 32 CFR part 220, estimated to be published October 1, 1997, will eliminate the high cost ancillary services' dollar threshold (by changing it from $25 to $0) and the associated term ''high cost ancillary service.'' In anticipation of that change, the phrase ''high cost ancillary service'' has been replaced with the phrase ''ancillary services requested by an outside provider.'' The elimination of the threshold ipso facto eliminates the bundling of costs whereby a patient was billed if the total ancillary services costs in a day (defined as 0001 hours to 2400 hours) exceeded $25.00.

[8] Charges for ancillary services requested by an outside provider (physicians, dentists, etc.) are relevant to the Third Party Collection Program. Third party payers (such as insurance companies) shall be billed for ancillary services when beneficiaries who have medical insurance obtain services from the MTF that are prescribed by providers external to the MTF. Laboratory and Radiology procedure costs are calculated using the Physicians' Current Procedural Terminology (CPT)–4 Report weight multiplied by either the laboratory or radiology multiplier (section III.J). Eligible beneficiaries (family members or retirees with medical insurance) are not personally liable for this cost and shall not be billed by the MTF. MSA patients, who are not beneficiaries as defined by 10 U.S.C. 1074 and 1076, are charged at the ''Other'' rate if they are seen by an outside provider and come to the MTF for services. Final rule of 32 CFR Part 220, estimated to be published October 1, 1997, will eliminate the high cost ancillary services' dollar threshold (by changing it from $25 to $0) and the associated term ''high cost ancillary service.'' In anticipation of that change, the phrase ''high cost ancillary service'' has been replaced with the phrase ''ancillary services requested by an outside provider.'' The elimination of the threshold ipso facto eliminates the bundling of costs whereby a patient was billed if the total ancillary services costs in a day (defined as 0001 hours to 2400 hours) exceeded $25.00.

[9] The attending physician is to complete the CPT–4 code to indicate the appropriate procedure followed during cosmetic surgery. The appropriate rate will be applied depending on the treatment modality of the patient: Ambulatory procedure visit, outpatient clinic visit or inpatient surgical care services.

[10] Family members of active duty personnel, retirees and their family members, and survivors shall be charged elective cosmetic surgery rates. Elective cosmetic surgery procedure information is contained in Section III G. The patient shall be charged the rate as specified in the FY98 reimbursable rates for an episode of care. The charges for elective cosmetic surgery are at the full reimbursement rate (designated as the ''Other'' rate) for inpatient per diem surgical care services in section I.B., ambulatory procedure visits as contained in section III.C, or the appropriate outpatient clinic rate in section II A–K. The patient is responsible for the cost of the implant(s) and the prescribed cosmetic surgery rate. NOTE: The implants and procedures used for the augmentation mammaplasty are in compliance with Federal Drug Administration guidelines.

[11] Each regional lipectomy shall carry a separate charge. Regions include head and neck, abdomen, flanks, and hips.

[12] These procedures are inclusive in the minor skin lesions. However, CHAMPUS separates them as noted here. All charges shall be for the entire treatment, regardless of the number of visits required.

[13] Dental service rates are based on a dental rate multiplier times the American Dental Association (ADA) code and the DoD established weight for that code.

[14] Ambulance charges shall be based on hours of service in 15 minute increments. The rates listed in section III.I are for 60 minutes or 1 hour of service. Providers shall calculate the charges based on the number of hours (and/or fractions of an hour) that the ambulance is logged out on a patient run. Fractions of an hour shall be rounded to the next 15 minute increment (e.g., 31 minutes shall be charged as 45 minutes).

[15] Air in-flight medical care reimbursement charges are determined by the status of the patient (ambulatory or litter) and are per patient. The charges are billed only by the Air Force Global Patient Movement Requirement Center (GFMRC).

2. Department of Health and Human Services

For the Department of Health and Human Services, Indian Health Service, effective October 1, 1997 and thereafter:

	Hospital Care Inpatient Day	
General Medical Care	Alaska	$1,702
	Rest of the United States	1,049
	Outpatient Medical Treatment	
Outpatient Visit	Alaska	340
	Rest of the United States	209

3. Department of Veterans Affairs

For the Department of Veterans Affairs, effective October 1, 1997 and thereafter:

	Tortiously liable rates	Interagency rates
Hospital Care, Rates Per Inpatient Day		
General Medicine:		
Total	$1208	$1098
Physician	145	.....
Ancillary	315	.....
Nursing, Room, and Board	748	.....
Neurology:		
Total	1154	1042
Physician	169	.....
Ancillary	305	.....

	Tortiously liable rates	Interagency rates
Nursing, Room, and Board	680	.....
Rehabilitation Medicine:		
Total	808	729
Physician	92	.....
Ancillary	247	.....
Nursing, Room, and Board	469	.....
Blind Rehabilitation:		
Total	957	873
Physician	77	.....
Ancillary	475	.....
Nursing, Room, and Board	405	.....
Spinal Cord Injury:		
Total	886	801
Physician	110	.....
Ancillary	223	.....
Nursing, Room, and Board	553	.....
Surgery:		
Total	2079	1904
Physician	229	.....
Ancillary	631	.....
Nursing, Room, and Board	1219	.....
General Psychiatry:		
Total	557	518
Physician	54	.....
Ancillary	91	.....
Nursing, Room, and Board	432	.....
Substance Abuse (Alcohol and Drug Treatment):		
Total	333	300
Physician	32	.....
Ancillary	77	.....
Nursing, Room, and Board	224	.....
Intermediate Medicine:		
Total	396	356
Physician	19	.....
Ancillary	58	.....
Nursing, Room, and Board	319	.....
Nursing Home Care, Rates Per Day		
Nursing Home Care:		
Total	299	270
Physician	9	.....
Ancillary	40	.....
Nursing Room, and Board	250	.....
Outpatient Medical and Dental Treatment		
Outpatient Visit:		
Total	229	211
Emergency Dental	143	127
Outpatient Visit Prescription Filled	25	25

For the period beginning October 1, 1997, the rates prescribed herein superseded those established by the Director of the Office of Management and Budget, October 31, 1996 (61 FR 56360).

Franklin D. Raines,

Director, Office of Management and Budget.

[FR Doc. 97–27629 Filed 10–16–97; 8:45 am]

BILLING CODE 3110–01–P

PENSION BENEFIT GUARANTY CORPORATION

Submission of Information Collection for OMB Review; Comment Request; Payment of Premiums

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Notice of request for extension of OMB approval.

SUMMARY: The Pension Benefit Guaranty Corporation (''PBGC'') is requesting that the Office of Management and Budget (''OMB'') extend approval, under the Paperwork Reduction Act, of the collection of information under its regulation on Payment of Premiums (29 CFR Part 4007), including Form 1–ES, Form 1, and Schedule A to Form 1, and related instructions (OMB control number 1212–0009; expires February 28, 1998). The collection of information also includes a certification (on Schedule A) of compliance with requirements to provide certain notices to participants under the PBGC's regulation on Disclosure to Participants (29 CFR Part 4011), and surveys of plan

administrators to assess compliance with those requirements. This notice informs the public of the PBGC's request and solicits public comment on the collection of information.

DATES: Comments should be submitted by November 17, 1997.

ADDRESSES: Comments should be mailed to the Office of Information and Regulatory Affairs of the Office of Management and Budget, Attention: Desk Officer for Pension Benefit Guaranty Corporation, Washington, DC 20503. The request for extension will be available for public inspection at the Communications and Public Affairs Department of the Pension Benefit Guaranty Corporation, suite 240, 1200 K Street, NW., Washington, DC, 20005–4026, between 9 a.m. and 4 p.m. on business days.

Copies of the collection of information may be obtained without charge by writing to the PBGC's Communications and Public Affairs Department at the address given above or calling 202–326–4040. (For TTY and TDD, call 800–877–8339 and request connection to 202–326–4040). The premium payment regulation can be accessed on the PBGC's home page at http://www.pbgc.gov.

FOR FURTHER INFORMATION CONTACT: Deborah C. Murphy, Attorney, or Harold J. Ashner, Assistant General Counsel, Office of the General Counsel, Pension Benefit Guaranty Corporation, 1200 K Street, NW., Washington, DC 20005–4026, 202–326–4024. (For TTY and TDD, call 800–877–8339 and request connection to 202–326–4024).

SUPPLEMENTARY INFORMATION: Section 4007 of Title IV of the Employee Retirement Income Security Act of 1974 (''ERISA'') requires the Pension Benefit Guaranty Corporation (''PBGC'') to collect premiums from pension plans covered under Title IV pension insurance programs. Pursuant to ERISA section 4007, the PBGC has issued its regulation on Payment of Premiums (29 CFR Part 4007). Section 4007.3 of the premium payment regulation requires plans, in connection with the payment of premiums, to file certain forms prescribed by the PBGC, and § 4007.10 requires plans to retain and make available to the PBGC records supporting or validating the computation of premiums paid.

The forms prescribed are PBGC Form 1–ES and Form 1 and (for single-employer plans only) Schedule A to Form 1. Form 1–ES is issued, with instructions, in the PBGC's Estimated Premium Payment Package. Form 1 and Schedule A are issued, with instructions, in the PBGC's Annual Premium Payment Package.

The premium forms are needed to determine the amount and record the payment of PBGC premiums, and the submission of forms and retention and submission of records are needed to enable the PBGC to perform premium audits. The plan administrator of each pension plan covered by Title IV of ERISA is required to file one or more of the premium payment forms each year. The PBGC uses the information on the premium payment forms to identify the plans paying premiums and to verify whether plans are paying the correct amounts. That information and the retained records are used for audit purposes.

In addition, section 4011 of ERISA and the PBGC's regulation on Disclosure to Participants (29 CFR Part 4011) require plan administrators of certain underfunded single-employer pension plans to provide an annual notice to plan participants and beneficiaries of the plans' funding status and the limits on the Pension Benefit Guaranty Corporation's guarantee of plan benefits. The participant notice requirement only applies (subject to certain exemptions) to plans that must pay a variable rate premium. In order to monitor compliance with Part 4011, plan administrators must indicate on Schedule A to Form 1 that the participant notice requirements have been complied with. The PBGC has also conducted surveys of plan administrators to assess compliance.

The collection of information under the regulation on Payment of Premiums, including Form 1–ES, Form 1, and Schedule A to Form 1, and related instructions has been approved by OMB under control number 1212–0009 through February 28, 1998. This collection of information also includes the certification and surveys of compliance with the participant notice requirements (but not the participant notices themselves). The PBGC is requesting that OMB extend its approval of this collection of information for another three years. (The participant notices constitute a different collection of information that has been separately approved by OMB.)

Under the Retirement Protection Act of 1994, certain special premium rules for regulated public utility company plans cease to apply for plan years beginning after 1997. The premium forms and instructions are being revised for 1998 to reflect this change. The revised forms and instructions will also include provisions regarding the use of electronic funds transfers as an optional form of payment for premiums and for PBGC payment of premium refunds, and will permit plan administrators whose filings are prepared by consultants to request that the PBGC no longer send them unneeded forms packages. In addition, reporting of plan-to-plan transfers will now be required only where the transferor plan ceases to exist, rather than in all cases.

The 1998 forms and instructions will eliminate multiple repetition of the rules regarding the date as of which the premium is calculated by using a new defined term, ''premium snapshot date,'' for this purpose. Instructions and line items for variable-rate premium exemptions (which are relatively brief) are being placed before those for non-exempt filing methods to save exempt filers from having to read through the relatively lengthy filing method descriptions.

The 1998 Form 1 will also give plans a way to notify the PBGC of their participation in the PBGC's new premium ''self-audit'' program. Under this program, plans could elect to engage independent auditors to review their premium filings as part of the regular plan audit cycle. The PBGC expects to announce details about the ''self-audit'' program within the next few months.

Other appropriate revisions (*e.g.*, clarifying and editorial changes) are also being made.

The PBGC estimates that it receives responses annually from about 49,500 plan administrators and that the total annual burden of the collection of information is about 4,042.5 hours and $11,236,125.

Issued in Washington, DC, this 15th day of October, 1997.

David M. Strauss,

Executive Director, Pension Benefit Guaranty Corporation.

[FR Doc. 97–27705 Filed 10–16–97; 8:45 am]

BILLING CODE 7708–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. IC–22848; File No. 812–10732]

Alexander Hamilton Life Insurance Company of America, et al.

October 9, 1997.

AGENCY: Securities and Exchange Commission (the ''SEC'' or the ''Commission'').

ACTION: Notice of application for exemption pursuant to Section 26(b) of the Investment Company Act of 1940 (the ''1940 Act'') approving a proposed substitution of securities and pursuant to Section 17(b) of the 1940 Act granting

exemptions from the provisions of Section 17(a)(1) and 17(a)(2) of the 1940 Act.

SUMMARY OF APPLICATION: Applicants seek an order pursuant to Section 26(b) of the 1940 Act approving the substitution of shares of certain registered management investment companies (''Substituted Funds'') for shares of certain other registered management investment companies currently serving as underlying investment options for variable annuity contracts and variable life insurance policies (''Replaced Funds''). Applicants also seek an order, pursuant to Sections 6(c) and 17(b) of the 1940 Act, granting exemptions from Section 17(a) to permit Applicants to carry out certain of the substitutions wholly or partly in-kind.

Applicants: Alexander Hamilton Life Insurance Company of America (''AH Life''), Alexander Hamilton Variable Annuity Separate Account (''AH Separate Account'') (together, the ''AH Applicants''), Chubb Life Insurance Company of America (''Chubb Life''), Chubb Separate Account A (''Chubb Separate Account'') (together, the ''Chubb Applicants''), Jefferson-Pilot Life Insurance Company (''JP Life'') and Jefferson-Pilot Separate Account A (''JP Separate Account'') (together, the ''JP Applicants'') (hereinafter referred to collectively as the ''Applicants,'' ''Life Company Applicants,'' and ''Separate Account Applicants'' as appropriate).

Filing Date: The application was filed on July 22, 1997, and amended on October 1, 1997.

Hearing or Notification of Hearing: An order granting the application will be issued unless the Commission orders a hearing. Interested persons may request a hearing on this application by writing to the Secretary of the SEC and serving Applicants with a copy of the request, in person or by mail. Hearing requests must be received by the Commission by 5:30 p.m. on November 3, 1997, and accompanied by proof of service on the Applicants in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the interest, the reason for the request and issues contested. Persons may request notification of the date of a hearing by writing to the Secretary of the SEC.

ADDRESSES: Secretary, SEC, 450 Fifth Street, NW., Washington, DC 20549. Applicants, Shari J. Lease, Esq., Chubb Life Insurance Company of America, One Granite Place, Concord, New Hampshire 03301.

FOR FURTHER INFORMATION CONTACT: Zandra Y. Bailes, Senior Counsel, or Mark C. Amorosi, Branch Chief, Office of Insurance Products, Division of Investment Management, at (202) 942–0670.

SUPPLEMENTARY INFORMATION: Following is a summary of the application. The complete application is available for a fee from the Public Reference of the SEC, 450 Fifth Street, NW., Washington, DC 20549 (tel. (202) 942–8090).

Applicants' Representations

1. The Life Company Applicants are affiliated stock life insurance companies wholly owned by Jefferson Pilot Corporation. Jefferson-Pilot Corporation acquired AH Life on October 6, 1995, with an effective date of September 30, 1995. The purchase of Chubb Life was closed on May 13, 1997, with an effective date of April 30, 1997.

2. AH Life, a stock life insurance company organized under the insurance laws of Michigan, is engaged primarily in the sale of annuity contracts and life insurance policies. AH Life is the sponsor and depositor of the AH Separate Account.

3. Chubb Life, a stock life insurance company chartered under the laws of Tennessee and redomesticated to New Hampshire on July 1, 1991, is authorized to write life insurance business in Puerto Rico, the U.S. Virgin Islands, Guam, the Commonwealth of the Northern Mariana Islands, the District of Columbia, and all states of the United States except New York. Chubb Life is the sponsor and depositor of the Chubb Separate Account.

4. JP Life, a stock life insurance company organized under the insurance laws of North Carolina, is primarily engaged in the writing of whole life, term, endowment, and annuity policies on an individual ordinary basis, plus industrial and group insurance. JP Life is the sponsor and depositor of the JP Separate Account.

5. The Separate Account Applicants are segregated asset accounts registered under the 1940 Act as unit investment trusts. The AH Separate Account is used to fund certain variable annuity contracts issued by AH Life and is divided into eight sub-accounts, seven of which invest in corresponding series (each a ''Fund'') of the Alexander Hamilton Variable Insurance Trust (the ''Trust'') with the remaining sub-account investing in the Federated Prime Money Fund II of the Federated Insurance Series (''Federated Prime Money Fund II''). Chubb Separate Account is used to fund certain variable life insurance policies issued by Chubb Life and is divided into 13 sub-accounts, nine of which invest in corresponding series (each a ''Portfolio'') of the Chubb America Fund, Inc. (''CAF'') with the remaining sub-accounts investing in the Templeton International Fund of Templeton Variable Products Series Fund, the High Income Portfolio of Variable Insurance Products Fund (''Fidelity VIP''), the Contrafund Portfolio and the Index 500 Portfolio of Variable Insurance Products Fund II (''Fidelity VIPII''). JP Separate Account is used to fund certain variable annuity contracts issued by JP Life, and is divided into 16 sub-accounts, two of which invest in shares of the Trust, two of which invest in shares of Oppenheimer Variable Account Funds, eight of which invest in shares of Fidelity VIP and Fidelity VIPII, two of which invest in shares of The Alger American Fund, and two of which invest in shares of the MFS Variable Insurance Trust.

6. The Trust is an open-end management investment company, organized as a Massachusetts business trust. The Trust consists of seven Funds, each of which operates as a separate investment fund, that have differing investment objectives, policies, and sub-advisers. Shares of the Funds are currently available to the public only through the purchase of certain variable annuity contracts issued by AH Life and JP Life and to retirement plans qualified under the Internal Revenue Code of 1986, as amended (''qualified retirement plans''). Alexander Hamilton Capital Management, Inc. acts as the Trust's investment adviser and has retained other unaffiliated investment advisers to act as sub-advisers who provide the day-to-day portfolio management for each Fund.

7. CAF is an open-end, diversified management investment company incorporated in Maryland. Shares of CAF's Portfolios are available for purchase only by the divisions of Chubb Life's separate accounts and qualified retirement plans. Chubb Investment Advisory Corporation (''CIAC'') acts as CAF's investment manager and has retained other investment advisers to act as sub-advisers in providing the day-to-day portfolio management of each portfolio of CAF. CAF consists of nine Portfolios, each of which is a separate investment portfolio, that have differing investment objectives.

8. The Oppenheimer Bond Fund is one series of Oppenheimer Variable Account Funds which is organized as a Massachusetts business trust. Oppenheimer Variable Account Funds is a diversified open-end investment company consisting of nine separate funds. Shares of Oppenheimer Variable Account Funds are offered for purchase by insurance company separate

accounts as the investment medium for variable life insurance policies and variable annuity contracts. Oppenheimer Funds, Inc. acts as investment adviser for the Oppenheimer Bond Fund.

9. The Federated Prime Money Fund II is an investment portfolio of Federated Insurance Series, an open-end management investment company, which is organized as a Massachusetts business trust. Federated Advisers acts as investment adviser for Federated Prime Money Fund II.

10. Jefferson-Pilot Corporation, the parent company of the Life Company Applicants, and the Life Company Applicants have determined to maintain only one proprietary mutual fund as an underlying investment option for the variable annuity contracts (''Contracts'') and variable life insurance policies (''Policies'') issued by the Applicants as well as other variable life insurance policies and variable annuity contracts which the Applicants may offer in the future. Applicants state that it has been determined that CAF should be the surviving proprietary investment option. Applicants, therefore, are proposing the substitutions described in the application and summarized below (the ''Substitutions''). After the Substitutions have been effected, the Trust will be de-registered and will cease operations. Applicants will continue to offer certain unaffiliated funds as investment options.

11. Applicants state that CAF has been in existence since 1984 and as of March 31, 1997 had total net assets of $362.7 million. CIAC does not waive or assume any of the expenses of CAF. In contrast, the Trust has been in existence since 1994 and did not commence operations until February 1996. As of March 31, 1997, the Trust had net assets of $37.3 million. As a result of the Trust's small size, the Trust's investment adviser has voluntarily waived or assumed expenses for all of the Trust's Funds. Moreover, the Trust's Funds have not generated substantial interest among purchasers of the Contracts. The Life Company Applicants believe that the CAF Portfolios are generally more responsive to the preferences of purchasers of the Contracts, while offering a larger fund with similar investment objectives, providing a potential for economies of scale.

12. Applicants note that the one exception to substituting the CAF Portfolios relates to the CAF Bond Portfolio. Given the sale of Chubb Life to Jefferson-Pilot Corporation, the former owner of Chubb Life and Jefferson-Pilot Corporation have determined that Chubb Asset Managers, Inc. will no longer be available to act as sub-adviser for the CAF Bond Portfolio. It has been determined that the Oppenheimer Bond Fund provides a better investment alternative than continuation of the CAF Bond Portfolio with a new adviser.

13. In addition, the substitution involving the unaffiliated mutual fund, Federated Prime Money Fund II, is being proposed. The actual expense ratio of the CAF Money Market Portfolio is lower than that of the Federated Prime Money Fund II, and its performance is slightly better since inception.

The Proposed Transactions

1. The AH Applicants propose that AH Life substitute: (1) Shares of the Money Market Portfolio of CAF for shares of the Federated Prime Money Fund II; (2) shares of the Balanced Portfolio of CAF for shares of the Balanced Fund of the Trust; (3) shares of the Growth and Income Portfolio of CAF for shares of the Growth & Income Fund of the Trust; (4) shares of the Capital Growth Portfolio of CAF for shares of the Growth Fund of the Trust; (5) shares of the Emerging Growth Portfolio of CAF for shares of the Emerging Growth Fund for the Trust; (6) shares of the World Growth Stock Portfolio of CAF for shares of the International Equity Fund of the Trust; (7) shares of the Oppenheimer Bond Fund for shares of the Investment Grade Bond Fund of the Trust; and (8) shares of the Oppenheimer Bond Fund for shares of the High Yield Bond Fund of the Trust.

2. The Chubb Applicants propose that Chubb Life substitute shares of the Oppenheimer Bond Fund for shares of the Bond Portfolio of CAF.

3. The JP Applicants propose that JP Life substitute: (1) Shares of the Capital Growth Portfolio of CAF for shares of the Growth Fund of the Trust; and (2) shares of the Emerging Growth Portfolio of CAF for shares of the Emerging Growth Fund of the Trust.

4. Applicants state that each of the Life Company Applicants will redeem for cash or kind of the shares of each Replaced Fund that it currently holds on behalf of its applicable Separate Account Applicant at the close of business on the date selected for the Substitutions. It is anticipated that the redemptions of the Federated Prime Money Fund II, the Trust Investment Grade Bond Fund, the Trust High Yield Bond Fund and the CAF Bond Fund will be redeemed all for cash. The Trust Investment Grade Bond Fund, the Trust High Yield Fund, and the CAF Bond Fund will be replaced by the Oppenheimer Bond Fund. With regard to all other Replaced Funds, it is anticipated that redemptions will be partly or wholly in-kind, and thus purchases of the applicable Substituted Funds will be paid for partly or wholly with portfolio securities. Thus, the Replaced Funds whose shares will be redeemed wholly or partly in-kind are the Trust's Balanced, Growth and Income, Growth, Emerging Growth and International Equity Funds.

5. The Life Company Applicants, each on behalf of its applicable Separate Account Applicant, will simultaneously place a redemption request with each applicable Replaced Fund and a purchase order with each applicable Substituted Fund so that each purchase will be for the exact amount of the redemption proceeds. As a result, at all times, monies attributable to contract owners and policy owners (''Owners'') then invested in the Replaced Funds will remain fully invested and will result in no change in the amount of any Owner's contract or policy value, death benefit or investment in the applicable Separate Account Applicant.

6. The Trust will effect the redemptions-in-kind and the transfers of portfolio securities in a manner that is consistent with the investment objectives, policies and restrictions, and federal tax law and 1940 Act diversification requirements applicable to the Substituted Fund. AH Life and JP Life each will take appropriate steps to assure that the portfolio securities selected for redemptions-in-kind are suitable investments for the Substituted Funds.

7. Applicants state that the Life Company Applicants have undertaken to assume all transaction costs and expenses relating to the Substitutions, including any direct or indirect costs of liquidating the assets of the Replaced Funds so that the full net asset value of redeemed shares of the Replaced funds held by the each Separate Account Applicant will be reflected in the Owners' Policy values' accumulation unit or annuity unit values following the Substitutions.

8. As part of the Substitutions, AH Life will combine the sub-accounts invested in the Trust's Investment Grade Bond Fund and the Trust's High Yield Bond Fund and designate the continuing sub-account as the Oppenheimer Bond Fund Sub-account.

9. Each of the Life Company Applicants will supplement the prospectus for the applicable Separate Account Applicant to reflect the proposed Substitutions. Within five days after the Substitutions, the

Applicants will send to their respective Owners written notice of the Substitutions (the ''Notice'') identifying the shares of the Replaced Funds which have been eliminated and the shares of the Substituted Funds which have been substituted. Applicants will include in such mailing the prospectuses for the Substituted Funds and the applicable revised prospectus or supplement for the Contracts and Policies of the Separate Account Applicants describing the Substitutions. Owners will be advised in the Notice that for a period of 31 days from the date of the Notice, Owners may transfer all assets, as substituted, to any other available sub-account, without limitation, without charge and without any such transfer counting as one of the limited number of transfers permitted in a contract or policy year free of charge (''Free Transfer Period'').

10. Following the Substitution, Owners will be afforded the same contract rights, including surrender and other transfer rights with regard to amounts invested under the Contracts and Policies, as they currently have.

Applicants' Legal Analysis and Conditions

1. Section 26(b) of the 1940 Act provides, in pertinent part, that ''[i]t shall be unlawful for any depositor or trustee of a registered unit investment trust holding the security of a single issuer to substitute another security unless the Commission shall have approved such substitution.'' The purpose of Section 26(b) is to protect the expectation of investors in a unit investment trust that the unit investment trust will accumulate the shares of a particular issuer, and to prevent scrutinized substitutions which might, in effect, force shareholders dissatisfied with the substituted security to redeem their shares, thereby possibly incurring either a loss of the sales load deducted from initial purchase payments, an additional sales load upon reinvestment of the redemption proceeds, or both.

2. Applicants represent that the purposes, terms and conditions of the Substitutions are consistent with the principles and purposes of Section 26(b) and do not entail any of the abuses Section 26(b) was designed to prevent. Applicants submit that the Substitutions involving the Trust are appropriate solutions to the insufficient size of the Trust which makes it difficult to achieve consistent investment performance and reduce operating expenses. Given the longer operating history of CAF and attendant investment performance, as well as its much larger asset size and resultant lack of fee waivers or assumption of expenses, Applicants maintain that it is in the best interest of the Owners to have CAF act as an underlying investment option for the variable products as opposed to the Trust. With regard to the CAF Bond Portfolio, the Chubb Applicants represent that the unavailability of the current sub-adviser as a result of the sale of Chubb Life to Jefferson-Pilot Corporation supports the selection of the Oppenheimer Bond Fund as an alternative investment.

3. Applicants represent that the Substitution will not result in the type of costly forced redemption that Section 26(b) was designed to guard against and is consistent with the protection of investors and the purposes fairly intended by the 1940 Act for the following reasons: (a) The Replaced Funds have objectives, policies and restrictions sufficiently similar to the objectives of the Substituted Funds so as to continue to fulfill the Owners' objectives and risk expectations; (b) after receipt of the Notice informing an Owner of the Substitutions, an Owner may request that assets be reallocated to another sub-account or division selected by the Owner, and the Free Transfer Period provides sufficient time for Owners to consider their reinvestment options; (c) the Substitutions, in all cases, will take place at the net asset value of the respective shares, without the imposition of any transfer or similar charge; (d) the Life Company Applicants have undertaken to assume the expenses and transaction costs, including, but not limited to, legal and accounting fees and any brokerage commissions relating to the Substitution and are effecting the redemption of shares in a manner that attributes all transaction costs to the Life Company Applicants; (e) the Substitutions in no way will alter the insurance benefits to Owners or the contractual obligations of the Life Company Applicants; (f) the Substitutions in no way will alter the tax benefits to Owners; and (g) the Substitutions are expected to confer certain economic benefits on Owners by virtue of the enhanced asset size and lower expenses of the Substituted Funds, as described in the application.

4. Section 17(a)(1) of the 1940 Act prohibits any affiliated person of a registered investment company. Section 17(a)(2) of the 1940 Act prohibits any affiliated person of a registered investment company, or an affiliated person of such affiliated person, from selling any security or other property to such registered investment company, or an affiliated person of an affiliated person, from purchasing any security or other property from such registered investment company.

5. Applicants state that certain of the Substitutions will be effected, partly or wholly, through redemptions and purchases in-kind and may be deemed to entail the indirect purchase of shares of the related Substituted Funds with portfolio securities of the Replaced Funds, and the indirect sale of securities of the Replaced Funds for shares of the Substituted Funds, and thus may entail each such Fund in the purchase and sale of such securities, acting as principal, to the other Fund in contravention of Section 17(a).

6. Moreover, immediately following the Substitutions, AH Life will combine the sub-accounts invested in the Trust's Investment Grade Bond and High Yield Bond Funds and designate the continuing sub-account as the Oppenheimer Bond Fund Sub-Account. AH Life could be said to be transferring unit values between its sub-accounts. The transfer of unit values could be said to involve purchase and sale transactions between sub-accounts that are affiliated persons. The sale and purchase transactions between sub-accounts could be said to come within the scope of Sections 17(a)(1) and 17(a)(2) of the 1940 Act, respectively.

7. Section 17(b) of the 1940 Act provides that the Commission may, upon application, grant an order exempting any transaction from the prohibitions of Section 17(a) if the evidence establishes that: (a) The terms of the proposed transaction, including the consideration to be paid or received, are reasonable and fair and do not involve overreaching on the part of any person concerned; (b) the proposed transaction is consistent with the policy of each registered investment company concerned, as recited in its registration statement and reports filed under the 1940 Act; and (c) the proposed transaction is consistent with the general purposes of the 1940 Act.

8. Applicants represent that the terms of the proposed transactions: (a) Are reasonable and fair, including the consideration to be paid and received, and do not involve overreaching; (b) are consistent with the investment policies of the Replaced Funds of the Trust; and (c) are consistent with the general purposes of the 1940 Act. Applicants state that the transactions effecting the Substitutions will be effected in conformity with Section 22(c) of the 1940 Act and Rule 22c–1 thereunder. Moreover, Applicants state that, in effecting the redemptions in-kind and transfers, the Trust will comply with the requirements of Rule 17a–7 under the 1940 Act to the extent possible and the

procedures established thereunder by the Board of Trustees of the Trust. Applicants submit that Owner interests after the Substitution, in practical economic terms, will not differ in any measurable way from such interests immediately prior to the Substitution. In each case, Applicants assert that the consideration to be received and paid is, therefore, reasonable and fair.

9. Applicants assert that the investment objectives of each of the Substituted Funds are sufficiently similar to the investment objectives of the Replaced Funds. In this regard, the Substitutions are consistent with Commission precedent pursuant to Section 17 of the 1940 Act. Applicants also assert that the Substitutions are consistent with the general purposes of the 1940 Act, as enunciated in the Findings and Declaration of Policy in Section 1 of the 1940 Act. The proposed transactions do not present any of the issues or abuses that the 1940 Act is designed to prevent.

10. Section 6(c) of the 1940 Act provides that the Commission may grant an order exempting persons and transactions from any provision or provisions of the 1940 Act as may be necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policies and provisions of the 1940 Act. Applicants submit that the proposed transactions will be effected in a manner consistent with the public interest and the protection of investors, as required by Section 6(c) of the 1940 Act. Owners will be fully informed of the terms of Substitutions through the prospectus supplements and the Notice, and will have an opportunity to reallocate investments prior to and following the Substitutions.

Conclusion

Applicants assert that, for the reasons summarized above, the requested order approving the Substitutions and related transactions involving in-kind redemptions and the combination of certain separate account sub-accounts should be granted.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 97–27545 Filed 10–16–97; 8:45 am]

BILLING CODE 8010–01–M

SECURITIES AND EXCHANGE COMMISSION

[Release No. 35–26764]

Filings Under the Public Utility Holding Company Act of 1935, as Amended (''Act'')

October 10, 1997.

Notice is hereby given that the following filing(s) has/have been made with the Commission pursuant to provisions of the Act and rules promulgated thereunder. All interested persons are referred to the application(s) and/or declaration(s) for complete statements of the proposed transaction(s) summarized below. The application(s) and/or declaration(s) and any amendments thereto is/are available for public inspection through the Commission's Office of Public Reference.

Interested persons wishing to comment or request a hearing on the application(s) and/or declaration(s) should submit their views in writing by October 31, 1997, to the Secretary, Securities and Exchange Commission, Washington, D.C. 20549, and serve a copy on the relevant applicant(s) and/or declarant(s) at the address(es) specified below. Proof of service (by affidavit or, in case of an attorney at law, by certificate) should be filed with the request. Any request for hearing shall identify specifically the issues of fact or law that are disputed. A person who so requests will be notified of any hearing, if ordered, and will receive a copy of any notice or order issued in the matter. After said date, the application(s) and/or declaration(s), as filed or as amended, may be granted and/or permitted to become effective.

Western Resources, Inc. (70–9097)

Western Resources, Inc. (''WRI''), located at 818 Kansas Avenue, Topeka, Kansas 66612, a Kansas public utility holding company exempt under section 3(a) pursuant to rule 2 from all provisions of the Act except section 9(a)(2), has filed an application under sections 9(a)(2) and 10 of the Act in connection with a proposed sale of its gas utility operations.

WRI, itself a public utility company, is engaged through its Kansas Power & Light Company division in the generation, purchase, transmission, distribution and sale of electric energy in Kansas and the transportation and sale of natural gas predominantly in Kansas, with some small operations in Oklahoma. WRI provides retail electric service to approximately 329,000 customers in Kansas and northeastern Oklahoma. WRI also provides wholesale electric generation and transmission services to numerous municipal customers in Kansas, and, through interchange agreements, to surrounding integrated systems. WRI provides natural gas service to approximately 648,000 retail customers in Kansas and northeastern Oklahoma. WRI is regulated as a public utility with respect to retail electric and gas rates and other matters by the Kansas Corporation Commission (''KCC'') and with respect to retail gas rates and other matters by the Oklahoma Corporation Commission (''OCC''). WRI is also subject to the jurisdiction of the Federal Energy Regulatory Commission, including jurisdiction with respect to rates for sales of electricity for resale.

WRI has one utility subsidiary, Kansas Gas and Electric Company (''KGE'').[1] KGE provides retail electric service to approximately 277,000 residential, commercial and industrial customers in Kansas and wholesale electric generation and transmission services to numerous municipal customers in Kansas and, through interchange agreements, to surrounding integrated systems. KGE does not own or operate any gas properties. KGE has one active subsidiary, Wolf Creek Nuclear Operating Corporation (''Wolf Creek''), a Delaware Corporation which is 47% owned by KGE and operates the Wolf Creek Generating Station on behalf of the plant's owners, including KGE.[2] KGE is regulated as a public utility company with respect to retail electric rates and other matters by the KCC. It is also regulated by the Nuclear Regulatory Commission under the Atomic Energy Act of 1954, as amended, in connection with its ownership interest in Wolf Creek.

WRI also has numerous direct and indirect non-utility subsidiaries, including (1) Westar Capital, Inc. (''Westar Capital''), a Kansas corporation that is holding company for certain of WRI's non-regulated activities,[3] (2)

[1] WRI has entered into an Agreement and Plan of Merger dated February 17, 1997 with Kansas City Power & Light Company (''KCPL''), a public utility company which operates as an electric utility company in Kansas and Missouri (''KCPL Merger Agreement''). The KCPL Merger Agreement calls for KCPL to be acquired by WRI, after which, WRI would claim, or seek an order from the Commission granting, an exemption under Section 3(a).

[2] KGE has obtained no-action assurance from the Commission regarding its ownership interest in Wolf Creek. SEC No-Action Letter (June 26, 1995).

[3] Westar Capital's subsidiaries and affiliates are: (i) Hanover Compressor Company (offers compression services to the natural gas industry), (ii) Westar Financial Services, Inc. (funds activities of other WRI subsidiaries), (iii) Wing Columbia, L.L.C. (invests in power generation projects in Columbia, South America), (iv) WestSec, Inc.

Continued

Westar Energy, Inc. (''Westar Energy''), a Kansas corporation that provides energy related services to large commercial and industrial customers,[4] and (3) Mid Continent Market Center, Inc. (''MCMC''), a Kansas corporation that offers natural gas transportation, wheeling, parking, balancing and storage services to natural gas procedures.[5]

For the year ended December 31, 1996, WRI had consolidated operating revenues of approximately $2,047 billion, approximately $549 million of which was derived from the company's natural gas operations, approximately $1.197 billion of which was derived from its electric energy operations and approximately $301 million of which was derived from its non-utility activities. Consolidated assets of WRI and its subsidiaries at December 31, 1996 were approximately $6.65 billion, approximately $4.36 billion of which consisted of identifiable utility property, plant and equipment. WRI's common stock, $5.00 par value, is listed on the New York Stock Exchange. There were 65,220,373 shares of WRI common stock outstanding as of July 30, 1997.

ONEOK, Inc., is a Delaware corporation which, among other things, operates as a gas utility company (''ONEOK''). ONEOK has its principal office in Tulsa, Oklahoma. It engages through its divisions and subsidiaries in several aspects of the energy business, including local distribution of natural gas. ONEOK is a gas utility company as defined in Section 2(a)(4) of the Act and is presently neither an associate nor an affiliate of a public-utility holding company. Oklahoma Natural Gas Company, a division of ONEOK, and two subsidiaries, ONG Transmission Company and ONG Sayre Storage Company comprise a fully integrated intrastate natural gas gathering, storage, transmission and distribution operation that provides natural gas service to approximately 730,000 customers, primarily in Oklahoma. The operations of the division and two subsidiaries are consolidated for ratemaking purposes by the OCC. ONEOK also engages in a number of non-regulated energy-related businesses, including natural gas marketing and oil and gas exploration and production. As of May 31, 1997, there were 27,997,925 shares of ONEOK common stock outstanding. For the year ended August 31, 1996, ONEOK's operating revenues on a consolidated basis were approximately $1.224 billion, of which approximately $538 million was attributable to regulated natural gas distribution activities and approximately $686 million to gas marketing, gas processing, gas exploration, gas production and other operations. Consolidated assets of ONEOK and its subsidiaries at May 31, 1997 were $1.40 billion, of which approximately $678 million consists of its gas distribution property, plant and equipment.

WRI requests authorization to acquire up to (1) 9.9% of the outstanding common stock of WAI, Inc. (WAI), a newly-formed Oklahoma corporation,[6] and (2) shares of WAI's non-voting convertible preferred stock, which, when aggregated with the common stock, may amount to as much as 45% of the total capital stock of WAI (collectively, ''WAI Stock''). In return for the WAI Stock, and pursuant to an amended and restated agreement dated May 19, 1997 (the ''Agreement'') among WRI, WAI and ONEOK, WRI will transfer all of the assets of its Kansas and Oklahoma gas distribution operations and all of the outstanding capital stock of its MCMC and Westar Gas Marketing subsidiaries[7] (collectively, the ''WRI Gas Business'') to WAI (the ''Asset Transaction'').[8] ONEOK will then merge with and into WAI, with WAI as the surviving corporation (the ''Merger,'' and together with the Asset Transaction, the ''Transactions''), and WAI will be renamed ONEOK, Inc. (''New ONEOK'').[9]

Immediately following the Merger, the New ONEOK board of directors and management will be the same as that of ONEOK prior to the Merger, except for (i) the expansion of the board from 14 to 16 directors to allow the appointment two directors designated by WRI[10] and (ii) the appointment of five persons who are currently officers of WRI with respect to the WRI Gas Business (including officers of MCMC and Westar) as additional officers of New ONEOK, with comparable responsibilities.[11] New ONEOK will be subject to regulation with respect to rates and other corporate matters by KCC and OCC.

Upon consummation of the Transactions, on a fully diluted basis, after giving affect to the Transactions and based on the number of shares of ONEOK Common Stock outstanding as of December 12, 1996, WRI will hold 2,966,702 shares of New ONEOK Common Stock and 19,317,584 shares of Series A Convertible Preferred Stock of New ONEOK,[12] representing up to 9.9%

(engaged in the business of monitored home and business security systems), (v) Westar Limited Partners, Inc. (''Westar Limited'') (participates in limited partnerships and investments related to the business of WRI), (vi) Valence, L.L.C. (develops, manufactures, produces and distributes electronic parts, equipment and products), (vii) Thunderbird Limited, III, L.P. (a low income housing project in which Westar Limited is an 82% limited partner), (viii) Thunderbird Montery, L.P. (a low income housing project in which Westar Limited is a 99% limited partner), and (ix) Oakwood Manor, L.P. (a low income housing project in which Westar Limited is a 99% limited partner).

[4] Westar Energy's subsidiaries are: (i) Westar Energy Investments, Inc. (holds investments of Westar Energy), (ii) Westar Gas Marketing, Inc. (''Westar Gas Marketing'') (arranges natural gas purchasing, transportation and delivery for natural gas users), (iii) Westar Gas Company (gathers and processes natural gas in Oklahoma and Kansas), (iv) Indian Basin Venture I and II (collectively, Indian Basin Ventures) (operates a gas processing plant in New Mexico), (v) Westar Electric Marketing, Inc. (arranges electric marketing and brokering for commercial and industrial customers on a wholesale level), and (vi) Westar Business Services, Inc. (provides energy related services to commercial and industrial customers).

[5] MCMC has a subsidiary, Market Center Gathering, Inc., which facilitates the operation of gas gathering systems.

[6] WAI has been formed initially as a wholly-owned subsidiary of WRI.

[7] As noted above, MCMC provides natural gas transportation, wheeling, parking, balancing and storage services to natural gas producers and Westar Gas Marketing arranges natural gas purchasing, transportation and delivery for natural gas users.

[8] Applicant states that transfer of the WRI Gas Business to New ONEOK will improve the efficiency of WRI's gas utility operations, will be in the public interest and the interests of investors and consumers and will not be detrimental to the proper functioning of the resulting holding company system.

[9] Pursuant to a Registration Rights Agreement to be entered into by WRI and New ONEOK upon closing of the Transactions, the outstanding shares of ONEOK common stock (''ONEOK Common Stock'') will be converted on a one-for-one basis into the right to receive shares of New ONEOK common stock (''New ONEOK Common Stock''). Each share of New ONEOK Common Stock will be issued together with the corresponding number of associated rights to purchase one one-hundredths of a share of Series C Preferred Stock of New ONEOK.

[10] Only one of the two directors may be an officer, director or employee of WRI or its subsidiaries. The two directors to be designated by WRI approximate the number of directors it could elect in ordinary circumstances, based on its 9.9% common equity interest, if cumulative voting applied. No board member designated by WRI will serve on the New ONEOK board nominating committee, or chair any other committee of New ONEOK's board.

[11] Under certain circumstances, following the occurrence of a ''Regulatory Change,'' WRI has the right to designate additional directors providing for aggregate representation of up to one-third of the New ONEOK Board.

[12] Shares of Series A Convertible Preferred Stock are non-voting, except that they vote with the New ONEOK Common Stock (and any other class or series of stock which may be similarly entitled to vote with the holders of New ONEOK Common Stock) as a single class with respect to certain extraordinary matters such as transactions constituting a Change in Control (as defined in the Shareholder Agreement) or proposed changes to New ONEOK's Certificate or Incorporation or By-Laws. The Series A Convertible Preferred Stock is convertible, at the option of the holder, in whole or in part, at any time following the occurrence of a Regulatory Change (as defined in the Shareholder Agreement), into New ONEOK Common Stock at the rate of one share of New ONEOK Common Stock for each share of Series A Convertible Preferred Stock (as adjusted to reflect any stock

of the New ONEOK Common Stock outstanding before conversion of any of the Series A Convertible Preferred Stock into New ONEOK Common Stock and up to 45% of the New ONEOK Common Stock that would be outstanding after conversion of all such stock. The present shareholders of ONEOK Common Stock will hold shares of New ONEOK Common Stock representing at least 90.1% of the New ONEOK Common Stock then outstanding and not less than 55% of the New ONEOK Common Stock that would be outstanding after conversion of all of the Series A Convertible Preferred Stock to be held by WRI.

WRI and New ONEOK will enter into a shareholder agreement (''Shareholder Agreement''), upon the closing of the Transactions, which will place certain restrictions on WRI's actions as a New ONEOK shareholder during the term of the Shareholder Agreement.[13] Among other things, the Shareholder Agreement will provide that the ''Shareholder Group'' (defined as WRI, its affiliates, partners and certain other persons and groups contemplated by Section 13(d) of the Securities Exchange Act of 1934) will be prohibited from acquiring (1) any Voting Securities (as defined in the Shareholder Agreement) that would cause the Shareholder Group to have more than a 9.9% Voting Ownership Percentage,[14] prior to the occurrence of a Regulatory Change (as defined in the Shareholder Agreement),[15] or (2) any securities that would, at any time, cause the Shareholder Group's Total Ownership Percentage[16] to exceed the Maximum Ownership Percentage specified in the Shareholder Agreement.[17] The Shareholder Agreement gives the Shareholder Group certain ''top-up'' and ''dilutive issuance'' rights that enable the Shareholder Group to ensure that the Voting Ownership Percentage does not fall below 9.9% and the Total Ownership Percentage does not fall below the Maximum Ownership Percentage. The Shareholder Agreement will also impose certain restrictions on WRI's ability to vote[18] or transfer the securities of New ONEOK.

Applicant states that the proposed Transactions satisfy all of the requirements of Sections 9(a)(2) and 10 under the Act.[19] In addition, WRI and ONEOK have requested a no-action letter from the Commission in connection with the proposed Transactions seeking assurances that WRI's ownership interest in New ONEOK will not cause NEW ONEOK to be deemed a ''subsidiary'' of WRI or WRI to be deemed a ''holding company'' under the Act.

For the Commission, pursuant to delegated authority, by the Division of Investment Management.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 97–27522 Filed 10–16–97; 8:45 am]

BILLING CODE 8010–01–M

split or similar events). In addition, any shares of the Series A Convertible Preferred Stock transferred by WRI to any person other than WRI or its affiliates is required to be converted into New ONEOK Common Stock.

[13] The Shareholder Agreement terminates under certain circumstances described in Article V of the agreement.

[14] ''Voting Ownership Percentage'' means the Voting Power (as defined in the Shareholder Agreement) represented by New ONEOK Common Stock and shares of any other class of capital stock of New ONEOK then entitled to vote in the election of directors (not including Convertible Preferred Stock) (''Voting Securities'') beneficially owned by the person whose voting ownership percentage is being determined.

[15] The Shareholder Agreement states that a ''Regulatory Change'' will be deemed to have occurred upon the receipt by WRI of an opinion of counsel (which counsel must be reasonably acceptable to New ONEOK) to the effect that either (1) the 1935 Act has been repealed, modified, amended or otherwise changed or (2) WRI has received an exemption, or, in the unqualified opinion of WRI's counsel, is entitled without any regulatory approval to claim an exemption, or has received an approval or no-action letter from the Commission or its staff under the 1935 Act or has registered under the 1935 Act, or any combination of the foregoing, and as a consequence of (1) and/or (2), WRI may fully and legally exercise such rights under the Shareholder Agreement as take effect in the period after the Regulatory Change has occurred.

[16] ''Total Ownership Percentage'' means the Voting Power (as defined in the Shareholder Agreement) which would be represented by the Securities Beneficially Owned (as defined in the Shareholder Agreement) by the Person whose Total Ownership Percentage is being determined if all shares of Convertible Preferred Stock (as Defined in the Shareholder Agreement), or other Securities convertible into Voting Securities (as defined in the Shareholder Agreement), Beneficially Owned by such Person were converted into shares of Common Stock (or other Voting Security.

[17] The Shareholder Agreement defines ''Maximum Ownership Percentage'' as a Total Ownership Percentage of 45%, less the Voting Power (as defined under the Shareholder Agreement) represented by all Voting Securities (as defined in the Shareholder Agreement) transferred by the Shareholder Group during the term of the Shareholder Agreement, including the Voting Power represented by any shares of Convertible Preferred Stock which were converted into shares of New ONEOK Common Stock contemporaneously with such transfer pursuant to the terms of the Shareholder Agreement.

[18] Among other things, the Shareholder Agreement provides that, with respect to the election of directors to New ONEOK's board of directors, WRI will vote all New ONEOK Common Stock held by it in accordance with the recommendation of New ONEOK's nominating committee. The New ONEOK nominating committee recommends nominees to fill vacancies on the board, establishes procedures to identify potential nominees, recommends criteria for membership on the board, and recommends the successor chief executive officer when a vacancy occurs. The New ONEOK By-laws provide that the chief executive officer of New ONEOK must be elected by the affirmative vote of 80% of the directors of New ONEOK.

[19] Section 9(a)(2) makes it unlawful, without approval of the Commission under Section 10, ''for any person * * * to acquire, directly or indirectly, any security of any public utility company, if such person is an affiliate * * * of such company and of any other public utility or holding company, or will by virtue of such acquisition become such an affiliate.'' Commission approval under Section 9(a)(2) is required because WRI (which is already an affiliate of its subsidiary, KGE) will become an affiliate of New ONEOK as a result of the proposed Transactions.

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 22850; 812–10808]

Security First Trust, et al.; Notice of Application

October 10, 1997.

AGENCY: Securities and Exchange Commission (''SEC'').

ACTION: Notice of application for exemption under section 6(c) of the Investment Company Act of 1940 (the ''Act'') from section 15(a) of the Act.

Summary of Application: Signet Banking Corporation (''Signet''), parent of Virtus Capital Management, Inc. (''Subadviser''), has entered into an agreement and plan of merger with First Union Corporation (''First Union''). The indirect change in control of the Subadviser will result in the assignment, and thus the termination, of the existing subadvisory contract between Security First Investment Management Corporation (''Adviser'') on behalf of Security First Trust (''Fund''), and the Subadviser. The order would permit the implementation, without shareholder approval, of a new investment subadvisory agreement for a period of up to 120 days following the date of the change in control of the Subadviser (but in no event later than April 30, 1998). The order also would permit the Subadviser to receive all fees earned under the new subadvisory agreement following shareholder approval.

Applicants: Fund, Adviser, and the Subadviser.

Filing Dates: The application was filed on October 7, 1997. Applicants have agreed to file an amendment during the notice period, the substance of which is included in this notice.

Hearing or Notification of Hearing: An order granting the application will be issued unless the SEC orders a hearing. Interested persons may request a hearing by writing to the SEC's Secretary and serving applicants with a

copy of the request, personally or by mail. Hearing requests should be received by the SEC by 5:30 p.m. on November 4, 1997, and should be accompanied by proof of service on applicants in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the SEC's Secretary.

ADDRESSES: Secretary, SEC, 450 Fifth Street, NW., Washington, DC 20549. Applicants, c/o Rosemary D. Van Antwerp, Esq., Evergreen Keystone Investment Services Inc., 200 Berkeley Street, Boston, Massachusetts 02116.

FOR FURTHER INFORMATION CONTACT: John K. Forst, Attorney Advisor, at (202) 942–0569, or Mary Kay Frech, Branch Chief, at (202) 942–0564 (Office of Investment Company Regulation, Division of Investment Management).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained for a fee at the SEC's Public Reference Branch, 450 Fifth Street, NW., Washington, DC 20549 (tel. 202–942–8090).

Applicants' Representations

1. The Fund is a Massachusetts business trust registered under the Act as an open-end management investment company. The Fund currently offers two series, the Virtus Equity Series and Virtus U.S. Government Income Series (the ''Portfolios''), to the public. The Adviser and the Subadviser, a wholly-owned subsidiary of Signet, are investment advisers registered under the Investment Advisers Act of 1940. The Fund and the Adviser have entered into a sub-advisory agreement for the Portfolios.

2. On July 18, 1997, First Union entered into an agreement and plan of merger with Signet, under which Signet would be merged with and into First Union in exchange for shares of common stock of First Union in exchange for shares of common stock of First Union (the ''Transaction''). As a result of the Transaction, Signet will become a wholly-owned subsidiary of First Union and the Subadviser will remain a wholly-owned subsidiary of Signet. Applicants expect consummation of the Transaction on November 13, 1997.

3. Applicants request an exemption to permit implementation, prior to obtaining shareholder approval, of a new investment subadvisory agreement between the Adviser and the Subadviser, on behalf of the Fund, (''New Agreement''). The requested exemption will cover an interim period of not more than 120 days beginning on the date the Transaction is consummated and continuing through the date on which the New Agreement is approved or disapproved by the shareholders of each Portfolio, but in no event later than April 30, 1998 (the ''Interim Period''). Applicants state that the New Agreement will be identical in substance to the existing investment subadvisory agreement (''Existing Agreement''). The contractual rates chargeable for subadvisory services under the New Agreement will remain the same as under the Existing Agreement.

4. On October 7, 1997, the Fund's board of trustees held an in-person meeting to evaluate whether the terms of the New Agreement are in the best interests of the Fund and its shareholders. At the meeting, a majority of the members of the board, including a majority of members who are not ''interested persons'' of the Fund, as that term is defined in section 2(a)(19) of the Act (the ''Independent Trustees''), voted in accordance with section 15(c) of the Act to approve the New Agreement and to submit the New Agreement to the shareholders of each of the Portfolios at meetings expected to be held in February, 1998 (the ''Meetings'').

5. Applicants expect that proxy materials for the Meetings will be mailed during January 1998. Applicants believe that the requested relief is necessary to permit continuity of investment management for the Fund during the Interim Period and to prevent disruption of the services for the Fund.

6. Applicants also request an exemption to permit the Subadviser to receive from the Fund, upon approval by its shareholders, all fees earned under the New Agreement during the Interim Period. Applicants state that the fees paid during the Interim Period will be unchanged from the fees paid under the Existing Agreement.

7. Applicants propose to enter into an escrow arrangement with an unaffiliated financial institution. The fees payable to the Subadviser during the Interim Period under the New Agreement will be paid into an interest-bearing escrow account maintained by the escrow agent. The escrow agent will release the amounts held in the escrow account (including any interest earned): (a) To the Adviser only upon approval of the relevant New Agreement by the shareholders of the Portfolios; or (b) to the relevant Portfolio if the Interim Period has ended and its New Agreement has not received the requisite shareholder approval. Before any such release is made, the Independent Trustees of the Fund will be notified.

Applicants' Legal Analysis

1. Section 15(a) of the Act provides, in pertinent part, that it is unlawful for any person to serve as an investment adviser to a registered investment company, except pursuant to a written contract that has been approved by the vote of a majority of the outstanding voting securities of the investment company. Section 15(a) further requires the written contract to provide for its automatic termination in the event of its ''assignment.'' Section 2(a)(4) of the Act defines ''assignment'' to include any direct or indirect transfer of a contract by the assignor, or of a controlling block of the assignor's outstanding voting securities by a security holder of the assignor.

2. Applicants state that, following the completion of the Transaction, Signet will become a wholly-owned subsidiary of First Union. Applicants believe, therefore, that the Transaction will result in an ''assignment'' of the Existing Agreement and that the Existing Agreement will terminate by its terms upon consummation of the Transaction.

3. Rule 15a–4 provides, in pertinent part, that if an investment advisory contract with an investment company is terminated by an assignment in which the adviser does not directly or indirectly receive a benefit, the adviser may continue to serve for 120 days under a written contract that has not been approved by the company's shareholders, provided that: (a) The new contract is approved by that company's board of directors (including a majority of the non-interested directors); (b) the compensation to be paid under the new contract does not exceed the compensation that would have been paid under the contract most recently approved by the company's shareholders; and (c) neither the adviser nor any controlling person of the adviser ''directly or indirectly receives money or other benefit'' in connection with the assignment. Applicants state that because of the benefits to Signet, the Subadviser's parent, arising from the Transaction, applicants may not rely on rule 15a–4.

4. Section 6(c) provides that the SEC may exempt any person, security, or transaction from any provision of the Act, if and to the extent that such exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act. Applicants

believe that the requested relief meets this standard.

5. Applicants note that the terms and timing of the Transaction were determined by First Union and Signet and arose primarily out of business considerations beyond the scope of the Act and unrelated to the Fund and the Subadviser, including the time needed to obtain federal and state banking approvals for the Transaction. Applicants submit that it is in the best interests of shareholders of the Fund to avoid any interruption in services to the Fund, to allow sufficient time for the consideration and return of proxies, and to hold a shareholders meeting.

6. Applicants submit that the scope and quality of services provided to the Fund during the Interim Period will not be diminished. During the Interim Period, the Subadviser would operate under the New Agreement, which would be substantively the same as the Existing Agreement, except for its effective date. Applicants submit that if the personnel providing material services pursuant to the New Agreement change materially, the Subadviser will apprise and consult with the Fund's board of trustees to assure that the board (including a majority of the Independent Trustees) is satisfied that the services provided by the Subadviser will not be diminished in scope or quality. Accordingly, the Fund should receive, during the Interim Period, the same subadvisory services, provided in the manner, at the same fee levels as the Fund received before the Transaction.

7. Applicants contend that the best interests of shareholders of the Fund would be served if the Subadviser receives fees for its services during the Interim Period. Applicants state that the fees are essential to maintaining the subadviser's ability to provide services to the Fund. In addition, the fees to be paid during the Interim Period will be unchanged from the fees paid under the Existing Agreements, which have been approved by the shareholders of each respective Portfolio.

Applicants' Conditions

Applicants agree as conditions to the issuance of the exemptive order requested by the application that:

1. The New Agreement will have substantially the same terms and conditions as the Existing Agreement, except for its effective date.

2. Fees earned by the Subadviser in respect of the New Agreement during the Interim Period will be maintained in an interest-bearing escrow account, and amounts in the account (including interest earned on such paid fees) will be paid (a) to the Subadviser in accordance with the New Agreement, after the requisite shareholder approvals are obtained, or (b) to the respective Portfolio, in the absence of shareholder approval with respect to such Portfolio.

3. The Fund will hold a meeting of shareholders to vote on approval of the New Agreement on or before the 120th day following the termination of the Existing Agreement (but in no event later than April 30, 1998).

4. Either First Union or the Subadviser will bear the costs of preparing and filing the application, and costs relating to the solicitation of shareholder approval of the Fund necessitated by the Transaction.

5. The Subadviser will take all appropriate steps so that the scope and quality of advisory and other services provided to the Fund during the Interim Period will be at least equivalent, in the judgment of the Independent Trustees, to the scope and quality of services previously provided. If personnel providing material services during the Interim Period change materially, the Subadviser will apprise and consult with the board to assure that the board, including a majority of the Independent Trustees of the Fund, are satisfied that the services provided will not be diminished in scope or quality.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 97–27594 Filed 10–16–97; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meeting

''FEDERAL REGISTER'' CITATION OF PREVIOUS ANNOUNCEMENT: [62 FR 53040, October 10, 1997].

STATUS: Closed Meeting.

PLACE: 450 Fifth Street, N.W., Washington, D.C.

DATE PREVIOUSLY ANNOUNCED: October 7, 1997.

CHANGE IN THE MEETING: Time Change/Deletions.

The closed meeting scheduled for Tuesday, October 14, 1997, at 11:00 a.m. was changed to Tuesday, October 14, 1997, at 2:00 p.m. and the following items were not considered:

Institution of injunctive actions.

At times, changes in Commission priorities require alterations in the scheduling of meeting items. For further information and to ascertain what, if any, matters have been added, deleted or postponed, please contact: The Office of the Secretary (202) 942–7070.

Dated: October 15, 1997.

Jonathan G. Katz,

Secretary.

[FR Doc. 97–27755 Filed 10–15–97; 3:43 pm]

BILLING CODE 8010–01–M

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–39225; File No. SR–Phlx–97–32]

Self-Regulatory Organizations; Philadelphia Stock Exchange, Inc.; Order Granting Approval to Proposed Rule Change Respecting the Public Order Exposure System for PACE Orders

I. Introduction

On June 30, 1997, the Philadelphia Stock Exchange, Inc. (''Phlx'' or ''Exchange'') submitted to the Securities and Exchange Commission (''SEC'' or ''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change to extend the duration of its automatic execution system order exposure time period for eligible orders from the current 15 seconds to 30 seconds.

The proposed rule change was published for comment in Securities Exchange Act Release No. 38864 (July 23, 1997), 62 FR 40882 (July 30, 1997). No comments were received on the proposal. This order approves the proposed rule change.

II. Description

The operation of the Philadelphia Stock Exchange Automatic Communication and Execution (''PACE'') System is governed by Phlx Rule 229 (''PACE Rule''). The PACE System is the Exchange's automatic order routing and executing system for securities on its equity trading floor.

With respect to market orders entered into PACE, Supplementary Material .05 to the PACE Rule provides that, in ⅛ point markets or greater, round-lot market orders up to 500 shares and partial round-lot (''PRL'') market orders up to 599 shares (*i.e.*, orders that combine a round-lot with an odd-lot order) are stopped at the PACE Quote [3]

[1] 15 U.S.C. § 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The PACE Quote consists of the best bid/offer among the American, Boston, Cincinnati, Chicago, New York, Pacific and Philadelphia Stock Exchanges as well as the Intermarket Trading System/Computer Assisted Execution System (''ITS/CAES''). *See* PACE Rule.

at the time of their entry into PACE (''Stop Price'') in the Public Order Execution System (''POES''). In addition, market orders for more than 599 shares that a specialist voluntarily has agreed to execute automatically also are entitled to participate in POES.[4]

Supplementary Material .05 to the PACE Rule states that the purpose of stopping eligible market orders in POES is to allow such orders to receive an opportunity for price improvement. Supplementary Material .05 further states that if a stopped order is not executed within the applicable order exposure time period, or ''window,'' the order will be automatically executed at the Stop Price.

Upon its adoption in early 1995, POES utilizes a 15 second order exposure window.[5] Following Phlx Floor Procedure Committee (''FPC'') approval in December 1995, however, the Exchange increased the duration of the POES window from 15 to 30 seconds.[6] At this time, the Exchange proposes to codify the 30 second time period into Supplementary Material .05, which currently reflects a 15 second window. The Exchange has represented that it believes that extending the POES window to 30 seconds enables the specialist to better gauge the market and thus, improves the likelihood of price improvement. Moreover, the Exchange stated that it has learned, in its two years of experience with POES, that additional time is needed for a meaningful opportunity for price improvement to be afforded to such orders. In this regard, the Exchange represented that the 30 second window better enables the specialist to locate between-the-market interest and probe other market centers.[7]

III. Discussion

For the reasons discussed below, the Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange, and, in particular, with the requirements of Section 6(b).[8] In particular, the Commission believes the proposal is consistent with the Section 6(b)(5) requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest.[9]

As stated in the previous section, the purpose of the proposed rule change is to amend Supplementary Paragraph .05 to the PACE Rule in order to increase the duration of the Exchange's POES order exposure window from 15 to 30 seconds. Each regional exchange has incorporated an order exposure feature similar to POES into its automatic order execution system.[10] Initially, the Chicago Stock Exchange (''CHX'') and the Pacific Exchange (''PCX'') had adopted 30 second order exposure windows into their rules. The CHX and PCX, however, amended their rules in 1990 to reduce the duration of their order exposure windows from 30 to 15 seconds.[11]

In the order approving the CHX and PCX proposals, the Commission acknowledged that any decrease in the duration of an order exposure window would have an adverse effect on price improvement opportunities available to eligible orders, while having a positive effect on the timeliness of the execution of such orders.[12] The Commission's analysis of the appropriateness of these proposals therefore required a balancing of their positive and negative effects. The Exchange's current proposal to increase the duration of the POES window requires that a similar analysis be undertaken; namely, balancing the proposal's potential positive effect on price improvement opportunities for customers orders against any negative effect that it may have on the timeliness of customer order execution. In this regard, based upon the Exchange's representations of its experience with POES, the system's functionalities, and the realities of competition for order flow between markets, the Commission believes that the Exchange's proposal strikes an appropriate balance in that the positive effects of increased order exposure time should offset any negative effects on the efficiency of order execution.

With regard to opportunities for price improvement, the Commission notes that, as stated above, the Exchange has had experience with both 15 and 30 second order exposure windows. The Exchange has represented that this experience has indicated that a 15 second window often was insufficient to allow the specialist to attempt price improvement at all, while the additional time afforded by a 30 second window provided specialists with a more meaningful opportunity to do so. In light of the Exchange's experience, and absent any empirical evidence to the contrary, the Commission believes that the proposal is appropriate in that the increase in order exposure time should result in a concomitant, and beneficial, increase in the price improvement opportunities afforded by Phlx specialists to customer orders that are eligible for POES.

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[4] *See* Supplementary Material .05 to the PACE Rule.

[5] Securities Exchange Act Release No. 35283 (January 26, 1995), 60 FR 6333 (February 1, 1995) (File No. SR–Phlx–94–58).

[6] The Exchange has represented that by its oversight, this change was not filed with the SEC as a proposed rule change prior to its implementation pursuant to Section 19(b) of the Act and Rule 19b–4 thereunder. The Exchange contends that upon the discovery of this oversight in the course of drafting changes to the PACE Rule, the change was promptly filed with the SEC. *See* Securities Exchange Act Release No. 37479 (July 25, 1996), 61 FR 40276 (August 1, 1996) (File No. SR–Phlx–96–25). The Exchange has re-filed this change as a separate proposed rule change due to the withdrawal of File No. SR–Phlx–96–25. The Exchange represents that, to date, it has not distributed marketing material reflecting an order exposure window of 30 seconds.

The Commission notes that Section 19(b) of the Act provides that each self-regulatory organization is required to file any proposed rule change with the Commission and that no proposed rule change shall take effect unless approved by the Commission or otherwise permitted in accordance with its provisions.

[7] In addition, the Exchange previously had stated its reasoning behind the expansion of the POES window to 30 seconds in an amendment letter respecting File No. SR–Phlx–96–25. *See* Letter from Gerald D. O'Connell, Senior Vice President, Phlx, to Jennifer Choi, Attorney, SEC, dated July 19, 1996. Specifically, the Exchange stated that the FPC recognized that 15 seconds was often too short of a time period for the specialist to act. In this regard, specialists has informed the Exchange that by the time they noticed an order was stopped, it had been automatically executed. The Exchange further stated that its decision to expand the POES window to 30 seconds ''is rooted in the logical principle that more time means more opportunity for price improvement.'' *Id*.

[8] 15 U.S.C. § 78f(b).

[9] In approving the proposed rule change, the Commission notes that it has considered the proposed rule's impact on efficiency, competition, and capital formation. 15 U.S.C. § 78c(f).

[10] BSE Rules, Ch. XXXIII, Section 3(c); CHX Rules, Art. XX, Rule 37(b)(6); and Securities Exchange Act Release No. 27727 (February 22, 1990), 55 FR 7396 (March 1, 1990) (order approving amendment of order exposure feature to PCX's P/COAST automatic execution system). *See also* CSE Rule 11.9(o)(2) (requires exposure of any unexecuted portion of any market or marketable limit order not fully executed pursuant to the CSE's public agency guarantee). In addition, the CSE has adopted a price improvement policy that requires preferencing dealers either to: (1) expose eligible customer orders on the Exchange for a minimum of 30 seconds in greater than minimum variation markets; or (2) immediately execute the order at an improved price. CSE Rule 11.9(u), Interpretation and Policy .01.

[11] *See* Securities Exchange Act Release No. 27727, *supra* note 10 (order reducing CHX and PCX order exposure time periods from 30 to 15 seconds). *See also* Securities Exchange Act Release No. 28667 (November 30, 1990), 55 FR 50624 (December 7, 1990) (order approving change in order exposure time from 30 to 15 seconds in CSE Rule 11.9(o)(2).

[12] *See* Securities Exchange Act Release No. 27727, *supra* note 9.

Moreover, the Commission believes that the proposal should have a limited impact on the timeliness of order executions on the Phlx. In this regard, the Commission notes that under the proposal a specialist will maintain the ability to execute manually an order residing on POES prior to the expiration of the POES window. Accordingly, if the specialist determines that price improvement is unlikely to occur, the specialist may execute the order at the Stop Price prior to the end of the 30 second period. In addition, the effect of the proposal on the overall timeliness of Phlx executions is further limited by the fact that the POES window only is applicable to certain market orders and then only in ⅛ point markets or greater. Finally, the Commission believes that the competition between Phlx specialists and other markets for order flow should provide a continuing incentive for specialists to execute customer orders promptly, thereby serving to further alleviate any potential adverse impact that the proposal may have on the provision of timely executions of customer orders.

IV. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[13] that the proposed rule change (SR–Phlx–97–32) is approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[14]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 97–27544 Filed 10–16–97; 8:45 am]

BILLING CODE 8010–01–M

[13] 15 U.S.C. § 78s(b)(2).

[14] 17 CFR 200.30–3(a)(12).

STATE DEPARTMENT

[Public Notice No. 2615]

Overseas Security Advisory Council (OSAC) Meeting Notice; Closed Meeting

The Department of State announces a meeting of the U.S. State Department—Overseas Security Advisory Council on November 4, 5, and 6, at the U.S. Department of State, Washington, D.C. Pursuant to Section 10(d) of the Federal Advisory Committee Act and 5 U.S.C. 552b(c) (1) and (4), it has been determined the meeting will be closed to the public. Matters relative to classified national security information as well as privileged commercial information will be discussed. The agenda calls for the discussion of classified and corporate proprietary/security information as well as private sector physical and procedural security policies and protective programs at sensitive U.S. Government and private sector locations overseas.

For more information contact Nick Proctor, Overseas Security Advisory Council, Department of State, Washington, D. C. 20522–1003, phone: 202–663–0869.

Dated: September 26, 1997.

Gregorie W. Bujac,

Director of the Diplomatic Security Service.

[FR Doc. 97–27538 Filed 10–15–97; 8:45 am]

BILLING CODE 4710–24–M

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

Reports, Forms and Record Keeping Requirements; Agency Information Collection Activity Under OMB Review

AGENCY: Office of the Secretary, DOT.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act 1995 (44 U.S.C. Chapter 35), this notice announces that the Information Collection Request (ICR) abstracted below has been forwarded to the Office of Management and Budget (OMB) for review and comment. The ICR describes the nature of the information collection and its expected burden. The **Federal Register** Notice with a 60-day comment period soliciting comments on the following collection of information was published on October 29,1996 (61 FR 55835–55836) and a Notice of Final Determination was published on June 10, 1997 (62 FR 31655–31661).

DATES: Comments must be submitted on or before November 17, 1997.

FOR FURTHER INFORMATION CONTACT: For information about the submission to OMB, Form OMB 83–I, including supporting statements for this collection contact the US DOT Dockets, Room PL 401, Department of Transportation, 400 Seventh Street, SW., Washington, DC 20590, 1–800–647–5527. For Technical issues in the submission: Mr. Robert F. Schultz, Jr., Office of Motor Carrier Research and Standards, (202) 366–2718, Federal Highway Administration, Department of Transportation, 400 Seventh Street, SW., Washington, DC 20590. Office hours are from 7:45 a.m. to 4:15 p.m., E.T., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Federal Highway Administration (FHWA)

Title: Motor Carrier Regulatory Relief and Safety Demonstration Project.

OMB Number: 2125–0575.

Type of Request: Reinstatement, without change, of a previously approved collection for which approval has expired.

Affected Public: Motor Carriers operating commercial motor vehicles with a gross vehicle weight rating between 10,001 and 26,000 pounds in interstate commerce.

Abstract: The National Highway System Designation Act of 1995 (Payable–59, 109 Stat. 568) was signed by the President on November 28, 1995. Section 344 of the Act requires FHWA to implement a pilot program under which motor carriers operating commercial motor vehicles (CMS) with a gross vehicle weight rating between 10,001 and 26,000 pounds in interstate commerce may qualify for exemption from certain Federal Motor Carrier Safety Regulations (FMCSRS) (49 CFR part 325 *et seq.*). The Act directs the FHWA to establish criteria for admission to the pilot, and to monitor the performance of those participating in the pilot. Section 344 also states that ''[the Secretary] shall complete the review [of the pilot program] by the last day of the 3-year period beginning on the date of the enactment of this paragraph [November 28, 1995]. [On November 28, 1998] the Secretary shall, after notice and an opportunity for public comment, grant such exemptions or modify or repeal existing regulations to the extent appropriate.'' By this language, Congress has directed the FHWA in explicit terms. The agency is bound not to just conduct and evaluate the pilot, but to grant exemptions, and modify or repeal regulations, immediately upon its conclusion, save only the time necessary to solicit public comment. On August 28, 1996, the agency published a notice for this collection, providing a proposed plan for this Project, soliciting public comment on the proposed Project, and referring to the agency's intent to request emergency processing. On October 29, 1996, the FHWA published a Supplemental Notice seeking public comment on the specific issue of whether the rules of the Project would preempt conflicting laws of the States. In February 1997, OMB granted emergency approval to the collection requirements of this Project until August 31, 1997. On June 10, 1997 the agency published a Notice of Final Determination on the Project, providing

a comprehensive outline of the criteria for admission, the application process, and the terms of the agreement between the FHWA and participant motor carriers. The agency also indicated that the information collections requirements related to the Project had been approved through emergency processing by the OMB until August 31, 1997, and that approval on a permanent basis of the collection requirements of the Project would be sought.

Estimated Annual Burden Hours: 420.

Number of Respondents: 125.

ADDRESSES: Send comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725–17th Street, NW., Washington, DC 20503, Attention DOT Desk Officer. Comments are invited on: whether the proposed collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; the accuracy of the Department's estimate of the burden of the proposed information collection; ways to enhance the quality, utility and clarity of the information to be collected; and ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

Issued in Washington, DC, on October 10, 1997.

Vanester M. Williams,

Clearance Officer, United States Department of Transportation.

[FR Doc. 97–27613 Filed 10–16–97; 8:45 am]

BILLING CODE 4910–62–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Noise Exposure Map Notice; Receipt of Noise Compatibility Program and Request for Review; Charlotte/Douglas International Airport, Charlotte, NC

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice.

SUMMARY: The Federal Aviation Administration (FAA) announces its determination that the noise exposure maps submitted by the City of Charlotte for the Charlotte/Douglas International Airport under the provisions of Title I of the Aviation Safety and Noise Abatement Act of 1979 (Pub. L. 96–193) and 14 CFR part 150 are in compliance with the applicable requirements. The FAA also announces that it is reviewing a proposed noise compatibility program that was submitted for the Charlotte/Douglas International Airport under part 150 in conjunction with the noise exposure map, and that this program will be approved or disapproved on or before March 30, 1998.

EFFECTIVE DATES: The effective date of the FAA's determination on the noise exposure maps and the start of its review of the associated noise compatibility program is September 30, 1997. The public comment period ends December 1, 1997.

FOR FURTHER INFORMATION CONTACT: Thomas M. Roberts, Atlanta Airports District Office, Federal Aviation Administration, Campus Building, 1701 Columbia Avenue, Suite 2–260, College Park, Georgia 30337–2747, Telephone 404/305–7153. Comments on the proposed noise compatibility program should also be submitted to the above office.

SUPPLEMENTARY INFORMATION: This notice announces that the FAA finds that the noise exposure maps submitted for Charlotte/Douglas International Airport are in compliance with applicable requirements of part 150, effective September 30, 1997. Further, FAA is reviewing a proposed noise compatibility program for that airport which will be approved or disapproved on or before March 30, 1998. This notice also announces the availability of this program for public review and comment. Under section 103 of Title I of the Aviation Safety and Noise Abatement Act of 1979 (hereinafter referred to as ''the Act''), an airport operator may submit to the FAA noise exposure maps which meet applicable regulations and which depict noncompatible land uses as of the date of submission of such maps, a description of projected aircraft operations, and the ways in which such operations will affect such maps. The Act requires such maps to be developed in consultation with interested and affected parties in the local community, government agencies, and persons using the airport.

An airport operator who has submitted noise exposure maps that are found by FAA to be in compliance with the requirements of Federal Aviation Regulations (FAR) Part 150, promulgated pursuant to Title I of the Act, may submit a noise compatibility program for FAA approval which sets forth the measures the operator has taken or proposes for the reduction of existing noncompatible uses and for the prevention of the introduction of additional noncompatible uses.

The City of Charlotte submitted to the FAA on August 26, 1997, noise exposure maps, descriptions and other documentation which were produced during Charlotte/Douglas International Airport's FAR. Part 150 Study Update, August 1997. It was requested that the FAA review this material as the noise exposure maps, as described in section 103(a)(1) of the Act, and that the noise mitigation measures, to be implemented jointly by the airport and surrounding communities, be approved as a noise compatibility program under section 104(b) of the Act.

The FAA has completed its review of the noise exposure maps and related descriptions submitted by the City of Charlotte. The specific maps under consideration are Noise Exposure Map 1996 and Noise Exposure Map 2001 in the submission. The FAA has determined that these maps for the Charlotte/Douglas International Airport are in compliance with the applicable requirements. This determination is effective September 30, 1997. FAA's determination on an airport operator's noise exposure maps is limited to a finding that the maps were developed in accordance with the procedures contained in appendix A of FAR Part 150. Such determination does not constitute approval of the applicant's data, information or plans, or a commitment to approve a noise compatibility program or to fund the implementation of that program.

If questions arise concerning the precise relationship of the specific properties to noise exposure contours depicted on a noise exposure map submitted under section 103 of the Act, it should be noted that the FAA is not involved in any way in determining the relative locations of the specific properties with regard to the depicted noise contours, or in interpreting the noise exposure maps to resolve questions concerning, for example, which properties should be covered by the provisions of section 107 of the Act. These functions are inseparable from the ultimate land use control and planning responsibilities of local government. These local responsibilities are not changed in any way under part 150 or through FAA's review of noise exposure maps. Therefore, the responsibilities for the detailed overlaying of noise exposure contours onto the map depicting properties on the surface rests exclusively with the airport operator which submitted those maps, or with those public agencies and planning agencies with which consultation is required under section 103 of the Act. The FAA has relied on the certification by the airport operator, under § 150.21 of part 150, that the

statutorily required consultation has been accomplished.

The FAA has formally received the noise compatibility program for Charlotte/Douglas International Airport, also effective on September 30, 1997. Preliminary review of the submitted material indicates that it conforms to the requirements for the submittal of noise compatibility programs, but that further review will be necessary prior to approval or disapproval of the program. The formal review period, limited by law to a maximum of 180 days, will be completed on or before March 30, 1998.

The FAA's detail evaluation will be conducted under the provisions of 14 CFR part 150, § 150.33. The primary considerations in the evaluation process are whether the proposed measures may reduce the level of aviation safety, create an undue burden on interstate or foreign commerce, or be reasonably consistent with obtaining the goal of reducing existing noncompatible land uses and preventing the introduction of additional noncompatible land uses.

Interested persons are invited to comment on the proposed program with specific reference to these factors. All comments, other than those properly addressed to local land use authorities, will be considered by the FAA to the extent practicable. Copies of the noise exposure maps, the FAA's evaluation of the maps, and the proposed noise compatibility program are available for examination at the following locations:

Federal Aviation Administration, 800 Independence Avenue, SW, Room 617, Washington, DC 20591;

Federal Aviation Administration, Atlanta Airports District Office, Campus Building, 1701 Columbia Avenue, Suite 2–260, College Park, Georgia 30337–2747;

Ms. Carolyn Morehead, Reception Area, Charlotte/Douglas International Airport, Charlotte, North Carolina 28219.

Questions may be directed to the individual named above under the heading, **FOR FURTHER INFORMATION CONTACT**.

Issued in Atlanta, Georgia, September 30, 1997.

Dell T. Jernigan,

Manager, Atlanta Airports District Office.

[FR Doc. 97–27386 Filed 10–16–97; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket MSP–008]

Sea-Land Service, Inc.; Notice of Application To Increase Service in the Non-Contiguous Domestic Trade for Puerto Rico

Sea-Land Service, Inc. (Sea-Land), by application dated October 1, 1997, has applied for an increase in the authorized level of the service Sea-Land provides to the Commonwealth of Puerto Rico (Puerto Rico), pursuant to section 656(d) of Subtitle B, Title VI, of the Merchant Marine Act, 1936, as Amended (1936 Act). In support of its application, Sea-Land has provided information related to the growth of real gross product for the Commonwealth of Puerto Rico, as supplied to Sea-Land by the Planning Board of the Office of the Governor of Puerto Rico.

As originally approved, Sea-Land's authorized service level for Puerto Rico was 230,612 Twenty-foot Equivalent Units (TEUs), as of August 9, 1995. Based on increases in the gross product of Puerto Rico for Fiscal Year (FY) 1996 (July 1, 1995 to June 30, 1996) Sea-Land has asked for an additional 6,365 TEUs of authorized service. Based on increases in Puerto Rico's gross product for FY 1997 (July 1, 1996 to June 30, 1997), Sea-Land has asked for a second additional increase in authorized service of 6,365 TEUs. Additionally, Sea-Land has requested a third increase of 3,167 TEUs projected for the period July 1, to December 31, 1997. In summary, Sea-Land is seeking an increase of 16,167 TEUs in the trade to a total of 246,779 TEUs. A summation of Sea-Land's request is attached hereto as Table I.

Any person, firm or corporation having an interest in this application for increased service authorization, and who desires to submit comments concerning Sea-Land's application, is requested to provide those comments to the Secretary, Maritime Administration, Room 7210, Nassif Building, 400 Seventh Street, S.W., Washington, D.C. 20590. Such comments must be filed in triplicate and received no later than 5:00 pm Eastern Time November 17, 1997.

Dated: October 10, 1997.

By Order of the Maritime Administrator.

Joel C. Richard,

Secretary, Maritime Administration.

Sea-Land Service, Inc.; Requested Increases in Authorized Non-Contiguous Domestic Service for the Commonwealth of Puerto Rico

Original Grandfather authorization as of August 9, 1995: 230,612 TEUs

For Fiscal Year 1996 (July 1, 1995 to June 30, 1996).

Gross Product for FY 1996: +3.1 Percent.

Proration, August 9, 1995 to June 30, 1996 = 326/366 Days (1996 was a leap year) = .89

(.89) × (3.1) = 2.76 Percent.

Increase = (.0276) × (230,612) = 6,365 TEUs

Total for June 30, 1996 = 236,977 TEUs

For Fiscal Year 1997 (July 1, 1996 to June 30, 1997)

Gross Product for FY 1997: +2.8 Percent (Tentative)

Increase = (.028) × (236,977) = 6,635 TEUs

Total for June 30, 1997 = 243,612 TEUs

Projected Increase July 1, 1997 to December 31, 1997

Gross Product: +2.6 Percent (Projected)

July 1 to December 31=184 days 184/365 = .5

Proration, July 1 to December 31, 1997 = (.5) × (2.6) = 1.3 Percent.

Increase = (.013) × (243,977) = 3,167 TEUs

Total for December 31, 1997 = 246,779 TEUs

Total Requested Increase: 16,167 TEUs

[FR Doc. 97–27614 Filed 10–16–97; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. 96–100; Notice No. 1]

Tires and Rims Labeling

Correction

In notice document 96–33121 beginning on page 68812 in the issue of Monday, December 30, 1996, make the following correction:

On page 68813, in the first column, the OMB Clearance Number should read 2127–0503.

Dated: October 10, 1997.

L. Robert Shelton,

Associate Administrator for Safety Performance Standards.

[FR Doc. 97–27595 Filed 10–16–97; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. 97–057–NO1]

Reports, Forms, and Recordkeeping Requirements

AGENCY: National Highway Traffic Safety Administration (NHTSA), DOT.

ACTION: Request for public comment on proposed collections of information.

SUMMARY: Before a Federal agency can collect certain information from the public, it must receive approval from the Office of Management and Budget (OMB). Under new procedures established by the Paperwork Reduction Act of 1995, before seeking OMB approval, Federal agencies must solicit public comment on proposed collections of information, including extensions and reinstatements of previously approved collections.

This document describes one collection of information for which NHTSA intends to seek OMB approval.

DATES: Comments must be received on or before December 16, 1997.

ADDRESSES: Comments must refer to the docket and notice numbers cited at the beginning of this notice and be submitted to Docket Section, Room 5109, NHTSA, 400 Seventh St., SW., Washington, DC 20590. Please identify the proposed collection of information for which a comment is provided by referencing its OMB Clearance Number. It is requested, but not required, that 1 original plus 2 copies of the comments be provided. The Docket Section is open on weekdays from 9:30 a.m. to 4 p.m.

FOR FURTHER INFORMATION CONTACT: Complete copies of each request for collection of information may be obtained at no charge from Mr. Edward Kosek, NHTSA Information Collection Clearance Officer, NHTSA, 400 Seventh Street, SW., Room 5111, Washington, DC 20590. Mr. Kosek's telephone number is (202) 366–2589. Please identify the relevant collection of information by referring to its OMB Clearance Number.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995, before an agency submits a proposed collection of information to OMB for approval, it must publish a document in the **Federal Register** providing a 60-day comment period and otherwise consult with members of the public and affected agencies concerning each proposed collection of information. The OMB has promulgated regulations describing what must be included in such a document. Under OMB's regulations (at 5 CFR 1320.8(d)), an agency must ask for public comment on the following:

(i) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(ii) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(iii) how to enhance the quality, utility, and clarity of the information to be collected; and

(iv) how to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

In compliance with these requirements, NHTSA asks public comment on the following proposed collection of information:

49 CFR Part 571.218, Motorcycle Helmets

Type of Request—Extension of a currently approved clearance.

OMB Clearance Number—2127–0518.

Form Number—This collection of information uses no standard forms.

Requested Expiration Date of Approval—Three years from date of clearance.

Summary of the Collection of Information—NHTSA has issued Federal Motor Vehicle Safety Standard No. 218, Motorcycle Helmets, which establishes minimum performance requirements for helmets designed for use by motorcyclists and other motor vehicle users. Standard No. 218 requires that each helmet shall be labeled permanently and legibly (S5.6), in a manner such that the label(s) can be read easily without removing padding or any other permanent part.

Description of the Need for the Information and Proposed Use of the Information—NHTSA requires labeling information to ensure that helmet owners have important safety information. The information currently provided on the helmet from the labels includes the manufacturer's name or identification, model, size, month and year of manufacture, shell and liner construction of the helmet. The owners will also receive important information on caring for the helmet from the labels. Finally, the DOT symbol signifies the manufacturer's certification that the helmet meets all the requirements in the standard. Labeling is necessary for NHTSA to identify the helmet, particularly, if the helmet failed the compliance tests.

Description of the Likely Respondents (Including Estimated Number, and Proposed Frequency of Response to the Collection of Information)—NHTSA estimates that 24 manufacturers of motorcycle helmets offer their products for sale in the United States. The frequency of response to the collection of information depends on the number of helmets that each manufacturer sells.

Estimate of the Total Annual Reporting and Recordkeeping Burden Resulting from the Collection of Information—Currently, 24 manufacturers produce, on the average, a total of approximately 1,200,000 motorcycle helmets a year. NHTSA estimates that the total annual information collection burden on all manufacturers is 4,000 hours. NHTSA estimates that annualized costs on all manufacturers is $480,000.

Authority: 44 U.S.C. 3506(c); delegation of authority at 49 CFR 1.50.

Dated: October 1, 1997.

L. Robert Shelton,

Associate Administrator for Safety Performance Standards.

[FR Doc. 97–27596 Filed 10–16–97; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. 97–041; Notice 01]

Denial of Petition To Adopt a Federal Motor Vehicle Safety Standard To Require That New Vehicles Be Equipped With Technology (Computer Chips) Embedded in Ignition Keys To Deter Theft

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation.

ACTION: Denial of petition for rulemaking.

SUMMARY: This document denies the Consumers for Auto Reliability and Safety's (CARS) petition to adopt a Federal Motor Vehicle Safety Standard (FMVSS) to require that new motor vehicles be equipped with specific technology, such as computer chips in the ignition keys, to deter theft. CARS believes that the standard it proposed would ensure a safer and more effective means of deterring theft than the steering lock systems presently required by 49 CFR Section 571.114, Theft Protection.

The agency is denying this petition because it cannot mandate specific technologies that motor vehicle manufacturers are to use to deter theft. The definition of ''motor vehicle safety standard'' in the vehicle safety law limits the agency's discretion with respect to petitions that seek to specify the design of vehicles or equipment rather than their performance. In addition, the Department of Transportation (DOT) and the Department of Justice (DOJ) are currently assessing the existing theft prevention program to determine what, if any, changes are needed to further deter motor vehicle theft. Accordingly, the agency believes it would be premature to promulgate additional requirements before this comprehensive assessment is completed.

FOR FURTHER INFORMATION CONTACT: Ms. Rosalind Proctor, Motor Vehicle Theft Group, Office of Planning and Consumer Programs, NHTSA, 400 Seventh Street, S.W., Washington, D.C. 20590. Ms. Proctor's telephone number is (202) 366–0846. Her fax number is (202) 493–2739.

SUPPLEMENTARY INFORMATION: By facsimile dated April 21, 1997, CARS petitioned the agency to adopt a new Federal Motor Vehicle Safety Standard (FMVSS) which will require new motor vehicles to be equipped with specific technology, such as computer chips embedded in the ignition keys, to deter theft. CARS believes that adopting such a standard would reduce crime and ensure a safer and more effective means of deterring theft than that offered by the steering lock systems presently required by 49 CFR Section 571.114, Theft Protection. Additionally, CARS notes that the European Union has mandated that model year (MY) 1999 vehicles must use some form of this technology to deter motor vehicle theft in its market. CARS contention is that adopting the proposed standard would be compatible with the agency's goal of moving toward harmonization with other countries without jeopardizing a stronger U.S. standard.

Agency Analysis

Because there is already a standard (FMVSS 114) covering theft protection, the agency is treating CARS' petition as a petition to amend the existing standard rather than to adopt a new standard as the petitioner requests. FMVSS 114 specifies requirements primarily for theft protection to reduce the incidence of crashes resulting from unauthorized operation of motor vehicles, or from rollaway of parked vehicles. Specifically, this standard requires that each vehicle have a key-locking system that requires the vehicle transmission lever to be in ''park'' before removal of the key is permitted; and that, whenever the key is removed, prevents the vehicle from starting, and prevents the steering and/or forward mobility of the vehicle.

Although NHTSA is interested in actions that would reduce motor vehicle theft and provide for a safer and more effective means of deterring theft than that presently offered by steering lock systems, the definition of ''motor vehicle safety standard'' in the vehicle safety law, 49 U.S.C. 30102(9), provides that a safety standard is ''a minimum standard for motor vehicle or motor vehicle equipment performance.'' This definition limits the agency's discretion with respect to petitions that seek to specify the design of vehicles or equipment rather than their performance. This prohibits the agency from mandating specific technologies that motor vehicle manufacturers are to use to deter theft, as the CARS petition requests.

In addition to FMVSS 114, Congress and NHTSA recognized the economic impact and seriousness of motor vehicle theft and have taken actions aimed at alleviating theft in a cost-effective manner. The Motor Vehicle Theft Law Enforcement Act (the Theft Act) was passed by Congress in 1984. The purpose of the Theft Act was to reduce the incidence of motor vehicle thefts and to facilitate the tracing and recovery of stolen motor vehicles and parts from stolen vehicles. The Department of Transportation implemented this legislation by issuing the Federal Motor Vehicle Theft Prevention Standard (49 CFR part 541), which requires manufacturers of designated high-theft passenger cars to inscribe or affix the vehicle identification number onto the major parts of that vehicle. In 1992, the Theft Act was amended to provide tougher law enforcement against auto theft, impede automobile title fraud, and extend the parts-marking requirements to light-duty trucks and multipurpose passenger vehicles.

49 CFR part 543, Exemption from Motor Vehicle Theft Prevention Standard, provides that manufacturers of high-theft vehicle lines may petition the agency for an exemption from the parts-marking requirements if an antitheft device is installed as standard equipment on the entire vehicle line. A manufacturer may be exempted from the parts-marking requirements for any line of passenger motor vehicles equipped with an antitheft system that is determined to be as effective in reducing and deterring theft as parts marking would be.

The exemption provisions of the Theft Act have already resulted in manufacturers installing antitheft systems, including systems that incorporate the technology advocated by CARS, in many high-theft models. Thus, vehicles with higher-than-median theft rates are already equipped with theft deterrents (parts marking and/or antitheft systems) that add to the protection provided by FMVSS No. 114.

All manufacturers are attempting to reduce motor vehicle theft through development and installation of effective antitheft devices as standard equipment. Additionally, along with meeting mandatory requirements, all manufacturers have moved forward in manufacturing new vehicles with other improved antitheft deterrents, such as hardened collars that shield the upper and lower casing of the steering column. These deter theft by increasing significantly the time required to disable the locking mechanism for the ignition, steering wheel and automatic transmission gear selector.

In its petition, CARS also asserts that by adopting a new FMVSS comparable to the European Union's, NHTSA would be meeting its goal of moving toward harmonization without jeopardizing the U.S. standard. The European Union has mandated that its model year (MY) 1999 vehicles must use some form of antitheft technology. Some manufacturers have already developed and installed antitheft devices which utilize specific ignition keys and sophisticated electronic control modules similar to that required by the European Union. The agency has also granted exemptions from parts marking under 49 CFR part 543 for models equipped with PASS-KEY and other antitheft devices with computer chips imbedded in the ignition key.

The statutory basis for granting these exemptions under the vehicle theft law is a finding by the agency, on a case-by-case basis, that these systems are at least as effective as the parts-marking requirements of the theft prevention standard in reducing and deterring theft (49 U.S.C. 33106(b). Part 543 does not specify how the antitheft device is to perform or be designed. Instead, it requires a manufacturer applying for an exemption to provide information on how the device is activated and functions. The agency then uses the information provided about these functions to decide whether the system will be sufficiently effective in deterring theft to warrant an exemption from the parts-marking requirements of the Theft Prevention Standard.

It should be noted that by October 25, 1997, the Department of Transportation is required to provide a Report to Congress which will evaluate the effects of federal regulations on auto theft and comprehensive insurance premiums, and recommend what changes, if any, to these regulations are appropriate. Specifically, the Report to Congress will evaluate the effects of the Anti Car Theft Act of 1992 and the Motor Vehicle Theft Law Enforcement Act of 1984. This report will provide information on the efficacy of parts-marking and antitheft devices. It will also recommend whether the Theft Prevention Standard should be continued without change, modified to cover more or fewer lines of passenger motor vehicles; modified to cover other classes of motor vehicles or to terminate the standard for all future motor vehicles. The notice seeking public review and comment on the report prior to its submission to Congress was published in the **Federal Register** on June 26, 1997 (See 62 FR 34494). The Department of Transportation and the Department of Justice are assessing the current theft prevention program to determine what, if any, changes are needed to further deter motor vehicle theft. Upon review of the public comments, recommendations for changes, if any, to the regulations will be considered.

The agency believes that the Theft Prevention Standard (49 CFR part 541), in conjunction with FMVSS No. 114 and Part 543, provides a comprehensive scheme for deterring motor vehicle theft. Until DOT and DOJ complete their assessment of the existing theft prevention program, it would be premature to promulgate any regulatory requirement under the vehicle safety law even if a way could be found to develop performance criteria rather than the design criteria suggested by the CARS petition.

In accordance with 49 CFR part 552, this completes the agency's review of the petition. The agency has concluded that there is no reasonable possibility that the request by the petitioner would be amended at the conclusion of a rulemaking proceeding. Accordingly, it denies CARS' petition.

Authority: 49 U.S.C. 30103, 30162; delegation of authority at 49 CFR 1.50 and 501.8

Issued on: October 9, 1997.

L. Robert Shelton,

Associate Administrator for Safety Performance Standards.

[FR Doc. 97–27597 Filed 10–16–97; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

Notice of Public Information Collection Submitted to OMB for Review

AGENCY: Surface Transportation Board, DOT.

ACTION: Reinstatement, without change of a previously approved collection for which approval has expired.

SUMMARY: The Surface Transportation Board has submitted to the Office of Management and Budget for review and approval the following proposal for collection of information as required by the Paperwork Reduction Act of 1995, Pub. L. 104–13 (44 U.S.C. Chapter 35).

Title: Annual Report form R–1 Class I Railroads.

OMB Form Number: 2140–0009.

No. of Respondents: 10.

Total Burden Hours: 8,000.

DATES: Persons wishing to comment on this information collection should submit comments by November 17, 1997.

ADDRESSES: Direct all comments to Case Control, Surface Transportation Board, 1925 K Street, NW, Washington, DC 20423. When submitting comments refer to the OMB number and title of the information collection.

FOR FURTHER INFORMATION CONTACT: Ward L. Ginn, Jr., 202 565-1533. Requests for copies of the information collection may be obtained by contacting Ellen R. Keys (202) 565–1675.

SUPPLEMENTARY INFORMATION: The Surface Transportation Board is, by statute, responsible for the economic regulation of surface transportation carriers operating in interstate and foreign commerce. The ICC Termination Act of 1995, Pub. L. No. 104–88, 109 Stat. 803 (1995), which took effect on January 1, 1996 abolished the Interstate Commerce Commission and transferred the responsibility for regulating rail transportation. Annual reports are required to be filed by Class I railroads pursuant to authority in Sections 49 U.S.C. 11145, 11144 and 11901 of the Act. The Board will use this information to monitor industry growth, company financial stability, traffic, and facilitate informed decision making.

Vernon A. Williams,

Secretary.

[FR Doc. 97–27604 Filed 10–16–97; 8:45 am]

BILLING CODE 4915–00–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[STB Finance Docket No. 33464]

Ashland Railway, Inc.—Acquisition and Operation Exemption—CSX Transportation, Inc.

Ashland Railway, Inc., a Class III rail common carrier, has filed a notice of exemption under 49 CFR 1150.41 to acquire and operate 25.85 route miles of rail line owned by the CSX Transportation, Inc. The track to be purchased, known as the Willard to Mansfield Line, extends from Mansfield, OH, milepost 61.07, to Willard,OH, milepost 86.92.

The transaction is expected to be consummated after the October 1, 1997 effective date of the exemption.

If the notice contains false or misleading information, the exemption is void *ab initio.* Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke does not automatically stay the transaction.

An original and 10 copies of all pleadings, referring to STB Finance Docket No. 33464, must be filed with the Surface Transportation Board, Office of the Secretary, Case Control Unit, 1925 K Street, N.W., Washington, DC 20423–0001. In addition, a copy of each pleading must be served on Richard R. Wilson, Esq., 1126 Eighth Avenue, Suite 403, Altoona, PA 16602.

Decided: October 8, 1997.

By the Board, David M. Konschnik, Director, Office of Proceedings.

Vernon A. Williams,

Secretary.

[FR Doc. 97–27601 Filed 10–16–97; 8:45 am]

BILLING CODE 4915–00–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[STB Finance Docket No. 33489]

Georgia Northeastern Railroad Company, Inc.—Lease and Operation Exemption—Georgia Department of Transportation

Georgia Northeastern Railroad Company, Inc., a Class III rail common carrier, has filed a notice of exemption under 49 CFR 1150.41 to lease from the Georgia Department of Transportation and operate three rail lines in the State of Georgia as follows: (i) From Valuation Station 20975+35 (milepost 382.47), at McCaysville, to Valuation Station 21726+83 (milepost 396.7), at Blue

Ridge, a distance of 14.23 miles in Fannin County; (ii) from Valuation Station 21726+83 (milepost 396.7), at Blue Ridge, to Valuation Station 22154+46 (milepost 404.8), at White Path, a distance of 8.1 miles in Fannin and Gilmer Counties; and (iii) from Valuation Station 21556+55 (milepost 393.47) on the north leg of the wye including the south leg of the wye, at Murphy Junction, to Valuation Station 21706+72 (milepost 396.32), in Mineral Bluff, a distance of 2.85 miles in Fannin County.

The transaction is expected to be consummated on or after the effective date of the exemption. Because the notice of exemption was filed on October 3, 1997, the transaction can be consummated no sooner than October 10, 1997.

If the notice contains false or misleading information, the exemption is void *ab initio*. Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke does not automatically stay the transaction.

An original and 10 copies of all pleadings, referring to STB Finance Docket No. 33489, must be filed with the Surface Transportation Board, Office of the Secretary, Case Control Unit, 1925 K Street, N.W., Washington, DC 20423–0001. In addition, a copy of each pleading must be served on Kevin R. Armbruster, Esq., Cushing, Morris, Armbruster & Jones, LLP, Suite 2110, International Tower, 229 Peachtree Street, N.E., Atlanta, GA 30303.

Decided: October 8, 1997.

By the Board, David M. Konschnik, Director, Office of Proceedings.

Vernon A. Williams,

Secretary.

[FR Doc. 97–27603 Filed 10–16–97; 8:45 am]

BILLING CODE 4915–00–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[STB Finance Docket No. 33487]

Iowa Northern Railway Company—Acquisition and Operation Exemption—Union Pacific Railroad Company

Iowa Northern Railway Company (IANR), a Class III rail carrier, has filed a verified notice of exemption under 49 CFR 1150.41 to acquire and operate an 8,692-foot portion of rail line, known as the Bristow Subdivision, owned by Union Pacific Railroad Company (UP), between the crossing of the UP and IANR lines at MP 288.8 and the end of the Bristow Subdivision at approximately MP 287.4 (end of track) to the east of that crossing in Clarksville, IA.[1] The transaction was expected to be consummated as soon as practicable after October 9, 1997, the effective date of the exemption.

If the notice contains false or misleading information, the exemption is void *ab initio*. Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the transaction.

An original and 10 copies of all pleadings, referring to STB Finance Docket No. 33487, must be filed with the Surface Transportation Board, Office of the Secretary, Case Control Unit,1925 K Street, NW, Washington, DC 20423–0001 and served on: David A. Hirsh, Harkins Cunningham, 1300 19th Street, N.W., Suite 600, Washington, DC 20036.

Decided: October 9, 1997.

By the Board, David M. Konschnik, Director, Office of Proceedings.

Vernon A. Williams,

Secretary.

[FR Doc. 97–27602 Filed 10–16–97; 8:45 am]

BILLING CODE 4915–00–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[STB Docket No. AB–534 (Sub-No. 1X)]

Lake State Railway Company—Abandonment Exemption—in Alpena County, MI

Lake State Railway Company (Lake State) has filed a notice of exemption under 49 CFR 1152 Subpart F—*Exempt Abandonments* to abandon its 8-mile line of railroad between milepost 0.0 near Alpena, and milepost 8.0 near Hillman, in Alpena County, MI. The line traverses United States Postal Service Zip Code 49707.

Lake State has certified that: (1) No local traffic has moved over the line for at least 2 years; (2) there has been no overhead traffic moving over the line during this time; (3) no formal complaint filed by a user of rail service on the line (or by a state or local government entity acting on behalf of such user) regarding cessation of service over the line either is pending with the Surface Transportation Board (Board) or with any U.S. District Court or has been decided in favor of complainant within the 2-year period; and (4) the requirements at 49 CFR 1105.7 (environmental reports), 49 CFR 1105.8 (historic reports), 49 CFR 1105.11 (transmittal letter), 49 CFR 1105.12 (newspaper publication), and 49 CFR 1152.50(d)(1) (notice to governmental agencies) have been met.

As a condition to this exemption, any employee adversely affected by the abandonment shall be protected under *Oregon Short Line R. Co.—Abandonment—Goshen*, 360 I.C.C. 91 (1979). To address whether this condition adequately protects affected employees, a petition for partial revocation under 49 U.S.C. 10502(d) must be filed. Provided no formal expression of intent to file an offer of financial assistance (OFA) has been received, this exemption will be effective on November 16, 1997, unless stayed pending reconsideration. Petitions to stay that do not involve environmental issues,[1] formal expressions of intent to file an OFA under 49 CFR 1152.27(c)(2),[2] and trail use/rail banking requests under 49 CFR 1152.29 must be filed by October 27, 1997. Petitions to reopen or requests for public use conditions under 49 CFR 1152.28 must be filed by November 6, 1997, with: Surface Transportation Board, Office of the Secretary, Case Control Unit, 1925 K Street, N.W., Washington, DC 20423.

A copy of any petition filed with the Board should be sent to applicant's representative: Kelvin J. Dowd, Esq., Slover & Loftus, 1224 Seventeenth Street, N.W., Washington, DC 20036.

If the verified notice contains false or misleading information, the exemption is void *ab initio*.

Lake State has filed an environmental report which addresses the abandonment's effects, if any, on the environment and historic resources. The Section of Environmental Analysis (SEA) will issue an environmental assessment (EA) by October 22, 1997. Interested persons may obtain a copy of the EA by writing to SEA (Room 500, Surface Transportation Board, Washington, DC 20423) or by calling SEA, at (202) 565–1545. Comments on environmental and historic preservation matters must be filed within 15 days

[1] IANR states that, although the official UP milepost designations suggest a track length of 1.4 miles, IANR personnel have measured the track length as 8,692 feet, or approximately 1.6 miles.

[1] The Board will grant a stay if an informed decision on environmental issues (whether raised by a party or by the Board's Section of Environmental Analysis in its independent investigation) cannot be made before the exemption's effective date. *See Exemption of Out-of-Service Rail Lines*, 5 I.C.C.2d 377 (1989). Any request for a stay should be filed as soon as possible so that the Board may take appropriate action before the exemption's effective date.

[2] Each offer of financial assistance must be accompanied by the filing fee, which currently is set at $900. *See* 49 CFR 1002.2(f)(25).

after the EA becomes available to the public.

Environmental, historic preservation, public use, or trail use/rail banking conditions will be imposed, where appropriate, in a subsequent decision.

Pursuant to the provisions of 49 CFR 1152.29(e)(2), Lake State shall file a notice of consummation with the Board to signify that it has exercised the authority granted and fully abandoned the line. If consummation has not been effected by Lake State's filing of a notice of consummation by October 17, 1998, and there are no legal or regulatory barriers to consummation, the authority to abandon will automatically expire.

Decided: October 9, 1997.

By the Board, David M. Konschnik, Director, Office of Proceedings.

Vernon A. Williams,

Secretary.

[FR Doc. 97–27600 Filed 10–16–97; 8:45 am]

BILLING CODE 4915–00–P

DEPARTMENT OF THE TREASURY

Departmental Office; Debt Management Advisory Committee; Meeting

The notice of the public meeting of the Treasury Borrowing Advisory Committee of The Bond Market Association that was announced in the **Federal Register** of October 7, 1997 (62 FR 52378) is hereby amended. The time of the meeting has been changed from 11:30 a.m. to 12:30 p.m. Eastern Time on October 28, 1997. The notification that was published on October 1 remains unchanged in all other respects.

October 10, 1997.

Gary Gensler,

Assistant Secretary (Financial Markets).

[FR Doc. 97–27543 Filed 10–16–97; 8:45 am]

BILLING CODE 4810–25–M

UNITED STATES INFORMATION AGENCY

Culturally Significant Objects Imported for Exhibition

Determinations

Notice is hereby given of the following determinations: Pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985, 22 U.S.C. 2459), Executive Order 12047 of March 27, 1978) 43 FR 13359, March 29, 1978), and Delegation Order No. 85–5 of June 27, 1985 (50 FR 27393, July 2, 1985), I hereby determine that the objects to be included in the exhibit, ''Flowers Underfoot: Indian Carpets of the Mughal Era'' (See list [1]), imported from abroad for the temporary exhibition without profit within the United States are of cultural significance. These objects are imported pursuant to a loan agreement with the foreign lenders. I also determine that the exhibition or display of the listed exhibit objects at The Metropolitan Museum of Art, New York, New York, from on or about November 17, 1997, to on or about March 1, 1998, is in the national interest. Public notice of these determinations is ordered to be published in the **Federal Register**.

Dated: October 10, 1997.

Les Jin,

General Counsel.

[FR Doc. 97–27591 Filed 10–16–97; 8:45 am]

BILLING CODE 8230–01–M

[1] A copy of this list may be obtained by contacting Ms. Carol B. Epstein, Assistant General Counsel, at 202/619–6981, and the address is Room 700, U.S. Information Agency, 301 Fourth Street, S.W., Washington, D.C. 20547–0001.

Corrections

Federal Register
Vol. 62, No. 201
Friday, October 17, 1997

This section of the FEDERAL REGISTER contains editorial corrections of previously published Presidential, Rule, Proposed Rule, and Notice documents. These corrections are prepared by the Office of the Federal Register. Agency prepared corrections are issued as signed documents and appear in the appropriate document categories elsewhere in the issue.

DEPARTMENT OF THE INTERIOR

National Park Service

Notice of Inventory Completion for Native American Human Remains in the Control of the National Park Service, Haleakala National Park, Makawao, HI

Correction

In notice document 97–27215, appearing on page 53652, in the issue of Wednesday, October 15, 1997, make the following correction:

On page 53652, in the third column, in the tenth line, ''*[thirty days after publication in the* **Federal Register**]'' should read ''November 14, 1997''.

BILLING CODE 1505-01-D

Federal Register

Friday
October 17, 1997

Part II

Department of Labor

Occupational Safety and Health Administration

29 CFR Part 1910

Occupational Exposure to Tuberculosis; Proposed Rule

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Part 1910

[Docket No. H–371]

RIN 1218–AB46

Occupational Exposure to Tuberculosis

AGENCY: Occupational Safety and Health Administration (OSHA), Labor

ACTION: Proposed rule and notice of public hearing.

SUMMARY: The Occupational Safety and Health Administration is proposing a health standard, to be promulgated under section 6(b) of the Occupational Safety and Health Act of 1970, 29 U.S.C. 655, to control occupational exposure to tuberculosis (TB). TB is a communicable, potentially lethal disease that afflicts the most vulnerable members of our society: the poor, the sick, the aged, and the homeless. As many as 13 million U.S. adults are presently believed to be infected with TB; over time, more than 1 million of these individuals may develop active TB disease and transmit the infection to others. TB remains a major health problem with 22,813 active cases reported in the U.S. in 1995. A number of outbreaks of this disease have occurred among workers in health care settings, as well as other work settings, in recent years. To add to the seriousness of the problem, some of these outbreaks have involved the transmission of multidrug-resistant strains of *Mycobacterium tuberculosis*, which are often fatal. Although it is the responsibility of the U.S. Public Health Service to address the problem of tuberculosis in the general U.S. population, OSHA is solely responsible for protecting the health of workers exposed to TB as a result of their job.

OSHA estimates that more than 5 million U.S. workers are exposed to TB in the course of their work: in hospitals, homeless shelters, nursing homes, and other work settings. Because active TB is endemic in many U.S. populations, including groups in both urban and rural areas, workers who come into contact with diseased individuals are at risk of contracting the disease themselves. The risk confronting these workers as a result of their contact with TB-infected individuals may be as high as 10 times the risk to the general population. Although the number of reported cases of active TB has slowly begun to decline after a resurgence between 1985–1992, 16 states reported an increase in the number of TB cases in 1995, compared with 1994. Based on a review of the data, OSHA has preliminarily concluded that workers in hospitals, nursing homes, hospices, correctional facilities, homeless shelters, and certain other work settings are at significant risk of incurring TB infection while caring for their patients and clients or performing certain procedures. To reduce this occupational risk, OSHA is proposing a standard that would require employers to protect TB-exposed employees by means of infection prevention and control measures that have been demonstrated to be highly effective in reducing or eliminating job-related TB infections. These measures include the use of respirators when performing certain high hazard procedures on infectious individuals, procedures for the early identification and treatment of TB infection, isolation of individuals with infectious TB in rooms designed to protect those in the vicinity of the room from contact with the microorganisms causing TB, and medical follow-up for occupationally exposed workers who become infected. OSHA has preliminarily determined that the engineering, work practice, and administrative controls, respiratory protection, training, medical surveillance, and other provisions of the proposed standard are technologically and economically feasible for facilities in all affected industries.

DATES: Written comments on the proposed standard must be postmarked on or before December 16, 1997 and notices of intention to appear at the informal rulemaking hearings must be postmarked on or before December 16, 1997.

Parties requesting more than 10 minutes for their presentation at the hearings and parties submitting documentary evidence at the hearing must submit the full text of their testimony and all documentary evidence no later than December 31, 1997.

The informal public hearings will begin at 10:00 a.m. on the first day of hearing and at 9:00 a.m. on each succeeding day. The informal public hearings will be held in Washington, D.C. and are scheduled to begin on February 3, 1998.

ADDRESSES: Hearings will be held in the Auditorium of the U.S. Department of Labor (Frances Perkins Building), 200 Constitution Avenue, NW, Washington, D.C. Subsequent additional informal public hearings will be held in other U.S. locations. A **Federal Register** notice will be issued upon determination of the locations and dates of these hearings.

Comments on the proposed standard, Notices of Intention to Appear at the informal public hearings, testimony, and documentary evidence are to be submitted in quadruplicate to the Docket Officer, Docket No. H–371, Room N–2625, U.S. Department of Labor, 200 Constitution Ave., NW, Washington, DC 20210, telephone (202) 219–7894. Comments of 10 pages or fewer may be transmitted by fax to (202) 219–5046, provided the original and three copies are sent to the Docket Officer thereafter. The hours of operation of the Docket Office are 10:00 a.m. until 4:00 p.m.

Written comments, Notices of Intention to Appear at the informal rulemaking hearings, testimony, documentary evidence for the hearings, and all other material related to the development of this proposed standard will be available for inspection and copying in the Docket Office, Room N–2625, at the above address.

FOR FURTHER INFORMATION CONTACT: Bonnie Friedman, Office of Information and Consumer Affairs, Occupational Safety and Health Administration, Room N–3647, U.S. Department of Labor, 200 Constitution Ave., NW, Washington, DC 20210, Telephone (202) 219–8148, FAX (202) 219–5986.

SUPPLEMENTARY INFORMATION:

Table of Contents

References to the rulemaking record are in the text of the preamble. References are given as ''Ex.'' followed by a number to designate the reference in the docket. For example, ''Ex. 1'' means exhibit 1 in the Docket H–371. This document is a copy of the petition for a permanent standard filed by the Labor Coalition to Fight TB in the Workplace on August 25, 1993. A list of the exhibits and copies of the exhibits are available in the OSHA Docket Office.

I. Introduction

The preamble to the Proposed Standard for Occupational Exposure to Tuberculosis discusses the events leading to the development of the proposed standard, the health effects of exposure to tuberculosis, and the degree and significance of the risk. An analysis of the technological and economic feasibility of the proposal and an explanation of the rationale supporting the specific provisions of the proposed standard are also included.

Public comment on all matters discussed in this notice and all other relevant issues is requested for the purpose of assisting OSHA in the development of a new standard for occupational exposure to tuberculosis.

A. Issues

OSHA requests comment on all relevant issues discussed in this preamble, including the health effects, risk assessment, significance of risk determination, technological and economic feasibility and requirements that should be included in the final standard. OSHA is especially interested in responses, supported by evidence and reasons, to the following questions. This list is provided to assist persons in formulating comments, but is not intended to be all inclusive or to indicate that participants need to respond to all issues or follow this format. Please give reasons for your answers and provide data when available.

Specific issues of concern to OSHA are the following:

Health Effects

1. What, if any, additional studies or case reports on TB should be included in the health effects analysis?

2. Is there information that will provide data for estimating the rise in Multidrug-resistant TB (MDR–TB)? Is the rise in MDR–TB a serious threat?

Risk Assessment

1. Are there alternative risk assessment methodologies available? What are they? Are there other studies available that would be useful for assessing risk?

2. Are there factors other than or in addition to the ones OSHA has chosen that would be useful in estimating the background risk for TB?

Technological and Economic Feasibility

1. Are OSHA's estimates of the numbers and types of workers currently exposed to *M. tuberculosis* reasonable? If not, please provide estimates of the number of workers currently at risk and the percentage of the total workforce these workers represent, by industry.

2. Are OSHA's estimates of controlled access rates (i.e., the percentage of workers currently at risk who would remain at risk after employers minimize the number of workers exposed to individuals with suspected or confirmed infectious TB) reasonable? If the number of workers exposed to individuals with suspected or confirmed infectious TB is minimized, by what percentage could the number of workers at risk be reduced in each affected industry? In each industry, what are the job categories that would continue to be occupationally exposed?

3. Are OSHA's estimates of the numbers of affected establishments reasonable? If not, please provide estimates of the number of affected establishments, by industry.

4. Are OSHA's estimates of occupational and job turnover rates reasonable? If not, please provide estimates of turnover rates for each of the affected industries.

5. Under what conditions would social work, social welfare services, teaching, law enforcement or legal services need to be provided to individuals identified as having suspected or confirmed infectious TB? What, if any, procedures could not be postponed until such individuals are determined to be noninfectious? How many workers in each of these categories may need to have contact with individuals with suspected or confirmed infectious TB under these conditions?

6. Using the proposed definition of ''suspected infectious TB,'' how many individuals with suspected infectious TB are likely to be encountered for every confirmed infectious TB case in each of the covered industries?

7. Are OSHA's estimates of the average number of suspected or confirmed infectious TB cases that would be transferred, per establishment in each industry, reasonable? If not, on average, how many TB cases per facility in each of the affected industries would be transferred?

8. How are individuals with suspected infectious TB transferred to establishments with AFB isolation facilities? Who pays for the transport of such cases, particularly for individuals transferred from homeless shelters? OSHA solicits comment on the feasibility of temporary AFB isolation facilities in homeless shelters and on methods that could be used to temporarily isolate individuals with suspected or confirmed infectious TB in homeless shelters.

9. Of the suspected infectious TB cases referred to hospitals from other facilities, how many are immediately ruled out without needing to be isolated?

10. Are OSHA's estimates of the number of necessary AFB isolation rooms reasonable? Are existing AFB isolation rooms reasonably accessible to facilities that transfer individuals with suspected or confirmed infectious TB?

11. What types of respirators are currently being used to protect workers against occupational exposure to *M. tuberculosis*?

12. Which of the NIOSH-approved N95 respirators meet all of the proposed criteria, including fit testing and fit checking criteria?

13. Are OSHA's estimates of respirator usage rates reasonable? For each of the covered industries, how often could respirators meeting the proposed requirements be reused and still maintain proper working condition? How often, on average, would respirators need to be replaced? Please specify the type of respirator.

14. OSHA has assumed, in its Preliminary Economic Analysis, that hospitals will have licensed health care professionals on-site to perform the medical procedures that would be required by the proposed rule, and that in the other industries, employees will have to travel off-site to receive the medical procedures. Which of the other affected industries typically have licensed health care professionals on site who could perform the required medical procedures? If employers were allowed two weeks to provide the medical procedures, rather than being required to provide them prior to initial assignment to jobs with occupational exposure, will it be less likely that employees will have to travel off site to receive these tests/procedures? What would the costs be if employees travel off-site for these tests/procedures?

15. Are OSHA's estimates of baseline compliance reasonable? If not, what types of controls are currently in place to protect workers against occupational exposure to *M. tuberculosis*, and what proportion of facilities in each of the affected industries currently are using such controls?

16. For facilities that have implemented controls to protect workers against occupational exposure to *M. tuberculosis*, how effective have such controls been in reducing the transmission of TB?

17. OSHA's Initial Regulatory Flexibility Analysis assesses the impacts of the proposed standard on small entities using the Small Business Administration's (SBA) size standards.

In addition, OSHA analyzed the impacts of the proposed standard on entities employing fewer than 20 workers. Are these definitions appropriate for the covered industries? If not, how should small entities be defined for each industry?

18. The SBA defines small government jurisdictions as ''governments of cities, counties, towns, townships, villages, school districts, or special districts with populations of less than 50,000.'' OSHA requests comment on the number of such small government jurisdictions.

19. Some parties have suggested that OSHA should allow the use of the CDC guidelines as an alternative to the proposed rule. However, OSHA believes that the CDC guidelines are not written in a regulatory format that would allow OSHA's Compliance Safety and Health Officers (CSHOs) to determine whether or not an employer is in compliance with the Guidelines. Others have suggested that OSHA could judge compliance with the guidelines by determining the number or rate of skin test conversions at the employer's facility. OSHA does not believe that smaller facilities have an adequate population for trends in test conversions to have any statistical validity. OSHA welcomes suggestions on any methods of making the CDC guidelines an enforceable alternative to an OSHA regulation or methods of measuring performance that could be applied across all types and sizes of facilities.

20. Because of the limited availability of data, OSHA characterized the risk in many sectors as similar to that in hospitals, and less than that documented in nursing homes and home health care. OSHA welcomes industry-specific data on test conversion rates or active case rates.

21. OSHA is unable to determine the effectiveness of specific elements of an effective infection control program in hospitals. OSHA welcomes any evidence on the relative effectiveness of individual elements in such programs, such as the identification and isolation of suspect cases, the use of engineering controls, the use of respirators, and employee training.

22. OSHA based its estimate of the effectiveness of infection control programs in other sectors on studies of the effectiveness of such programs in hospitals. OSHA welcomes any data concerning the effectiveness of OSHA's proposed infection prevention measures, or of other alternative infection control measures, in sectors other than hospitals.

23. SBREFA Panel members suggested a number of alternative approaches to the regulation. OSHA believes that it has at least partially adopted a number of these approaches. OSHA welcomes comments and suggestions on these approaches and the extent to which OSHA should further adopt them:

- Cooperative initiatives, such as expanding OSHA's current cooperative initiative with JCAHO;
- A federal-state government public health partnership to develop guidelines in various industry sectors;
- Performance standards developed with the assistance of federal, state, and local government, and labor and industry stakeholders;
- Separate approaches for the health and non-health industries (the approach for the health industries could be keyed to existing industry standards and that for non-health industries to guidelines);
- Different levels of compliance requirements for different industries, depending on their expertise, resources, and risk;
- Less stringent trigger mechanisms for the more burdensome portions of the standard; and
- Separate standards for each affected industry.

24. OSHA is proposing to include homeless shelters in the Scope of the standard. During the informal public hearings, OSHA intends to schedule a special session for participants to present additional information on homeless shelters. Also, OSHA is conducting a special study of the homeless shelter sector. The information gathered in the study will be placed in the docket for public comment. OSHA welcomes comment on any of the topics this study will cover including:

- Percentage of homeless persons that would meet OSHA's definition of a suspected infectious TB case (A breakdown of which symptoms are particularly common will help OSHA construct the best definition);
- Turnover among the homeless who use shelters;
- Employee turnover in homeless shelters;
- Trends in the number of homeless persons served in shelters.
- Criteria currently used by some homeless shelters to identify suspected infectious TB cases;
- Current practices used in homeless shelters to address TB hazards so that baseline compliance with the proposed standard can be determined. Of particular concern to OSHA are:

—Methods of isolation; and
—How suspected TB cases are handled.

- Feasibility of hospitals providing cards to the homeless indicating TB skin test status;
- Number of TB skin test conversions and active cases among the homeless and homeless shelter employees;
- Types of benefits offered to homeless shelter employees (e.g., health insurance);
- Economic feasibility:

—Costs of running a shelter;
—Revenue sources;
—How costs are accommodated as the number of homeless persons served increases; and
—Opportunities for cost pass-through;

- Number, location and types (e.g., family-oriented, walk-in, all-male) of homeless shelters;
- Number or proportion of homeless shelter workers who are unpaid volunteers; and
- The OSH Act applies to employees, not bona fide volunteers. However, OSHA understands that some states may, as a matter of law, require facilities to provide volunteers with protections established by OSHA standards. OSHA is seeking information on:

—Economic impacts in such states of covering volunteers (e.g., how costs would be handled, cost pass-through); and
—Protections currently offered to volunteers.

25. In what states, if any, do employers provide volunteers in the sectors affected by this proposed standard with the same protections as they provide to employees? How many volunteers might be affected by such requirements?

26. OSHA is concerned that medical removal protection and medical treatment of active cases of TB may have significant economic impacts on small firms that have an employee with an active case of TB. Is there any form of insurance available for covering the costs of medical removal protection or medical treatments required by the OSHA standard? Should OSHA consider phasing-in these provisions of the standard?

27. OSHA believes that substance abuse treatment centers, particularly in-patient treatment centers, normally have entry procedures that may include medical examinations. OSHA solicits comments on entry procedures for substance abuse treatment programs, the extent to which these entry procedures now include medical examinations, and the extent to which these examinations now include and examination for TB symptoms.

28. OSHA requests comment on the effects of extended compliance phase-in dates for the proposed requirements,

particularly for respirators, for small businesses and facilities relying on charitable and/or Medicare and Medicaid funding.

29. OSHA requests comment on all assumptions and estimates used in developing the Preliminary Economic Analysis. Please provide reasons and data to support suggested changes to the assumptions and estimates.

30. The World Health Organization (WHO) has launched an initiative to reduce active TB through the use of multi-drug therapy and using directly observed therapy. OSHA solicits comment on whether it should revise its risk assessment or any of its benefits estimates as a result of this initiative.

31. OSHA requests comment on the number of affected facilities that are tribally-operated, by industry.

General

1. A number of provisions in the proposed standard are triggered by the identification of an individual as having either ''suspected infectious tuberculosis'' or ''confirmed infectious tuberculosis.'' Of these provisions, are there some that should be triggered only once an individual has been identified as having ''confirmed infectious tuberculosis?'' If so, which provisions and why?

2. A number of the proposed standard's provisions require compliance or performance on an annual basis, e.g., reviews of the exposure control plan, the biosafety manual for laboratories, and the respiratory protection program; certification of biological safety cabinets; fit testing or a determination of the need for fit testing of respirators; medical histories, TB skin tests; and training. In addition, certain requirements must be performed on a semi-annual basis, e.g., inspection and performance monitoring of engineering controls, verification of air flow direction in laboratories, and, in some instances, TB skin testing. How can OSHA reduce the aggregate burden of these requirements, particularly in small entities, while still providing equal protection to employees? Of these annual and semi-annual provisions, which, if any, should be performed less frequently? Why and at what frequency? Which of these provisions, if any, should be performed more frequently? Why and at what frequency?

Scope

1. Is there information demonstrating risk of TB transmission for employees in work settings other than those included in the scope? Should OSHA, for example, expand the scope of this standard to cover all or some offices of general practitioners or dentists and if so, how? Should OSHA expand the scope to cover all teachers?

2. Are there provisions of the standard with which emergency medical services, home health care, and home-based hospice care employers cannot comply because their employees are at temporary work settings over which the employer has little or no control? If so, what are those provisions and why would an employer be unable to comply with them?

3. In covering only long-term care facilities for the elderly, is OSHA excluding similar facilities where there is increased risk of transmission of TB? If so, what are these facilities? Should OSHA include long-term care populations in addition to the elderly, such as long-term psychiatric care facilities? If so, what are these populations?

4. OSHA is proposing that employers provide medical management and follow-up for their employees who work in covered work settings, but who are not occupationally exposed, when they have an exposure incident resulting from an engineering control failure or similar workplace exposure. Is this the best way of assuring such employees receive medical management and follow-up?

5. OSHA is covering employees who have occupational exposure in covered work settings yet are not employees of the work setting (e.g., physician employed by another employer with hospital privileges, who is caring for a TB patient in the hospital). Can this be made more clear?

6. OSHA has proposed that facilities offering treatment for drug abuse be covered in the scope of the standard. Is coverage of such facilities appropriate? What factors unique to facilities that offer treatment for drug abuse would make compliance with the provisions of this proposed standard infeasible (e.g., would complying with certain provisions of the standard compromise the provision of services at facilities that offer treatment for drug abuse)?

Application

1. OSHA has proposed that an employer covered under the standard (other than an operator of a laboratory) may claim reduced responsibilities if he or she can demonstrate that his or her facility or work setting: (1) Does not admit or provide medical services to individuals with suspected or confirmed infectious TB; (2) has had no case of confirmed infectious TB in the past 12 months; and (3) is located in a county that, in the past 2 years, has had 0 cases of confirmed infectious TB reported in one year and fewer than 6 cases of confirmed infectious TB reported in the other year. Are there alternative methods that can be used to assure protection of employees in areas where infectious TB has not recently been encountered?

Exposure Control Plan

1. OSHA has proposed that the employer's exposure control plan contain certain policies and procedures. What, if any, policies and procedures should be added to the plan?

2. The proposed standard requires exposure incidents and skin conversions to be investigated, but does not require aggregate data regarding employee conversions to be collected and analyzed. Would the collection and analysis of aggregate data provide benefits beyond those provided by investigating each individual exposure incident or conversion? Why or why not? If aggregate data collection and analysis were required, what type of analysis should be required, at what analytical endpoint should employer action be required, and what should that action be?

3. OSHA has set forth the extent of responsibility for transfer of individuals based upon the type of work setting where such individuals are encountered. What are current practices regarding transfer of individuals with suspected or confirmed infectious TB in the work settings covered by the proposal?

Work Practices and Engineering Controls

1. Is OSHA's time limit of 5 hours following identification for transferring an individual with suspected or confirmed infectious TB to another facility or placing the individual into AFB isolation appropriate? If not, what is the maximum amount of time that an individual should be permitted to await transfer or isolation in a facility before the employer must implement the other provisions of the proposed standard?

2. OSHA has considered requiring facilities that encounter 6 or more individuals with confirmed infectious TB within the past 12 months to provide engineering controls in intake areas where early identification procedures are performed (e.g., emergency departments, admitting areas). Should this be a requirement? Are there types of controls, engineering or otherwise, that would be effective in controlling transmission in intake areas? Would the trigger of 6 individuals with confirmed infectious TB be appropriate?

3. Are there methods other than smoke trail testing and continuous monitors that would be effective for verifying negative pressure in AFB isolation rooms or areas?

4. OSHA is requiring engineering controls to be inspected and performance monitored every 6 months. Is this frequency appropriate?

5. OSHA is allowing exhaust air from AFB isolation rooms or areas where *M. tuberculosis* may be aerosolized that cannot feasibly be discharged directly outside to be HEPA-filtered and recirculated back into general ventilation. Is permitting such recirculation appropriate? If used, should there be any requirements to detect system failure?

6. OSHA is permitting stand-alone HEPA filter units to be used as a primary control measure. Is this appropriate? What, if any, methods other than ventilation and filtration can provide consistent protection?

7. Should ambulances that have carried an individual with suspected or confirmed infectious TB be required to be ventilated for a specific period of time or in a particular way before allowing employees to enter without a respirator? What engineering controls are available for ambulances?

Laboratories

1. The standard does not require labeling of laboratory specimens. Should OSHA require that laboratory specimens be labeled within the facility or when specimens are being shipped? If so, what should the label contain? Are there other agencies that require these specimens be labeled? What are these agencies and what is required?

2. OSHA has attempted to incorporate the CDC/NIH recommendations given in ''Biosafety in Microbiological and Biomedical Laboratories'' into the standard. Do any provisions need to be added in order for employees in clinical and research laboratories to be fully protected against exposures to *M. tuberculosis*?

Respirators

1. OSHA is requiring employees who are transporting an unmasked individual with suspected or confirmed infectious TB within a facility to wear a respirator. Is this appropriate? How often would an individual with suspected or confirmed infectious TB be transported unmasked through a facility? Under what circumstances would it be infeasible to mask such an individual? What other precautions should be taken when transporting such an individual who is not masked?

2. OSHA is requiring that maintenance personnel use respiratory protection during maintenance of air systems or equipment that may reasonably be anticipated to contain aerosolized *M. tuberculosis.* When would it be necessary to access such an air system at the time it was carrying air that may contain aerosolized *M. tuberculosis*? Should OSHA require that such air systems be purged and shut down whenever these systems are accessed for maintenance or other procedures?

3. OSHA has received information that the use of certain kinds of respirators in helicopters providing emergency medical services may hamper pilot communication. Have other air ambulance services encountered this problem? Does this problem exist when the employee is using a type N95 respirator or other types of respiratory protection such as powered air purifying respirators? What other infection control or industrial hygiene practices could be implemented to minimize employee exposure in these circumstances?

4. The CDC states that there may be selected settings and circumstances (e.g., bronchoscopy on an individual with suspected or confirmed infectious TB or an autopsy on a deceased individual suspected of having had active TB at the time of death) where the risk of transmission may be such that increased respiratory protection such as that provided by a more protective negative-pressure respirator or a powered air purifying respirator may be necessary. Are there circumstances where OSHA should require use of a respirator that is more protective than a type N95 respirator? If so, what are the circumstances and what type of respiratory protection should be required?

5. OSHA is proposing that respirators be fit-tested annually, which is consistent with general industrial hygiene practice, or, in lieu of an annual fit test, that employees have their need to receive the annual fit test be evaluated by the physician or other licensed health care professional, as appropriate. For the circumstances and conditions regulated by this standard, will the evaluation provide enough ongoing information about the fit of a respirator to be an adequate substitute for fit testing? Should OSHA require that an actual fit test be performed periodically? If so, at what frequency?

6. OSHA has not included any provisions regarding the use of supplied air respirators. Are there circumstances in which supplied air respirators would be used to protect against *M. tuberculosis*? Should OSHA include provisions addressing supplied air respirators in the standard?

7. OSHA is permitting the reuse of disposable respirators provided the respirator does not exhibit excessive resistance, physical damage, or any other condition that renders it unsuitable for use. Will the respirators continue to protect employees throughout the reuse period?

8. In the proposed standard for TB, OSHA has included separate provisions for all aspects of a respiratory protection program for tuberculosis. What other elements might need to be included? Which respiratory protection provisions, if any, are not appropriate for protection against TB? Please provide reasons and data to support inclusion or exclusion of particular provisions.

Medical Surveillance

1. Should any provisions be added to the Medical Surveillance program?

2. OSHA has not required that physical exams be included as part of the baseline evaluation. Is there information that is essential to medical surveillance for TB that can only be learned from a baseline physical exam?

3. OSHA is specifying tuberculin skin testing frequencies for employees with negative skin tests. Should tuberculin skin testing be administered more or less frequently? Are there other ways to determine the frequency of tuberculin skin testing?

4. OSHA is proposing that employees entering AFB isolation rooms or areas be skin tested every 6 months. However, employees providing home health care, home care, and home-based hospice care are to be skin tested annually. Employees entering the home of an individual who has suspected or confirmed infectious TB may have the same potential for exposure to aerosolized *M. tuberculosis* as employees who enter an isolation room. In light of this, should employees providing care to individuals with suspected or confirmed infectious TB in private homes be skin tested every 6 months?

5. OSHA is requiring that all tuberculin skin testing be administered, read, and interpreted by or under the supervision of a physician or other licensed health care professional, as appropriate, according to current CDC recommendations. Should OSHA require specific training for individuals who are administering, reading, and interpreting tuberculin skin tests? If so, what type of training should be required?

6. Should OSHA require a declination form for employees who do not wish to undergo tuberculin skin testing?

7. OSHA is including Medical Removal Protection (MRP) provisions for employees who are unable to wear respiratory protection or who contract infectious tuberculosis. Are there additional provisions that need to be included? What remedies are available to employees in states where worker compensation system do not consider occupational TB a compensable disease? What benefits are provided to workers who are unable to wear a respirator?

8. OSHA is requiring that employees who must wear a respirator be provided a face-to-face determination of their ability to wear the respirator. Does this determination need to be made through a medical evaluation or would the use of an appropriately designed questionnaire be adequate? What would be the advantages and disadvantages of relying on a questionnaire to make this determination? Are there sample questionnaires that have proven to be effective for determining an employee's ability to wear a respirator?

9. OSHA has drafted Medical Surveillance, paragraph (g), to explain first who must be provided with the protections listed in the paragraph and how the surveillance is to be administered and secondly, in paragraphs (g)(2), Explanation of Terms, and (g)(3), Application, how the general medical terms are to be construed to meet the standard and in what instances the medical examinations or tests are to be offered. The Agency realizes that there is some repetition in these paragraphs and seeks comment on whether there might be a better way to list the requirements.

Communication of Hazards and Training

1. OSHA is requiring that signs for isolation rooms and areas bear a ''STOP'' Sign and the legend ''No Admittance Without Wearing A Type N95 or More Protective Respirator.'' Is there another sign that would assure patient confidentiality while providing adequate notification of the hazard and the necessary steps to minimize the hazard for employees who may be inadvertently exposed?

2. OSHA is requiring that ducts be labeled ''Contaminated Air—Respiratory Protection Required.'' Should OSHA require that duct labels also include the ''STOP'' sign?

3. Is the labeling of ducts carrying air that may contain aerosolized *M. tuberculosis* (e.g., from isolation rooms and areas, labs) at all access points feasible? What, if any, equally protective alternative exists to permanent labeling in situations where an exhaust duct from a room may or may not be carrying air containing aerosolized *M. tuberculosis* (e.g., the exhaust duct would only be carrying aerosolized *M. tuberculosis* when an individual with infectious TB is being isolated in the room)?

Dates

1. OSHA has proposed that very small businesses with fewer than 20 employees be given an additional 3 months to comply with the standard's engineering control provisions (i.e., the start-up date for engineering controls for small businesses would be 270 days from the Effective Date of the standard). Are there other requirements of the proposed standard (e.g., respiratory protection) for which very small businesses should be given additional time to come into compliance? If so, for which provisions would they need additional time and why? Are 20 employees an appropriate cut-off for this purpose? Are there other employers that may need extended time to achieve compliance?

Definitions

1. A number of provisions in the standard are triggered by the identification of an individual as having ''suspected infectious tuberculosis.'' Under the definition of ''suspected infectious tuberculosis'', OSHA has proposed criteria that the Agency believes are the minimum indicators that, when satisfied by an individual, require an employer to consider that the individual may have infectious tuberculosis. Are there other criteria that should be included in this definition?

2. Coverage of an employee under the standard is based upon the definition of ''occupational exposure.'' Similar to OSHA's Bloodborne Pathogens standard, occupational exposure is dependent upon reasonable anticipation of contact with an individual with suspected or confirmed infectious tuberculosis or with air that may contain aerosolized *M. tuberculosis.* Are there additions that could be made to this definition that would help employers determine which of their employees are occupationally exposed?

3. OSHA has proposed requirements for research laboratories that differ from those of clinical laboratories. The standard includes definitions of ''research laboratory'' and ''clinical laboratory'' to assist the employer in differentiating between these two types of laboratory. Do the definitions clearly differentiate between these two types of laboratories? Should such a distinction be made? Are there any modifications that should be made to these definitions?

B. Information Collection Requirements

This proposed Tuberculosis standard contains collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA'95), 44 U.S.C. 3501 *et seq.* and the regulation at 5 CFR § 1320. PRA'95 defines collection of information to mean, ''the obtaining, causing to be obtained, soliciting, or requiring the disclosure to third parties or the public of facts or opinions by or for an agency regardless of form or format.'' [44 U.S.C. § 3502(3)(A)].

The title, description of the need for and proposed use of the information, summary of the collections of information, description of the respondents, and frequency of response of the information collection are described below with an estimate of the annual cost and reporting burden, as required by 5 CFR § 1320.5(a)(1)(iv) and § 1320.8(d)(2). Included in the estimate is the time for reviewing instructions, gathering and maintaining the data needed, and completing and reviewing the collection of information.

OSHA invites comments on whether the proposed collection of information:

(1) Ensures that the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Estimates the projected burden accurately, including whether the methodology and assumptions used are valid;

(3) Enhances the quality, utility, and clarity of the information to be collected; and

(4) Minimizes the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.

Title: Tuberculosis 29 CFR 1910.1035.

Description: The proposed Tuberculosis (TB) Standard is an occupational safety and health standard that will prevent or minimize occupational exposure to TB. The standard's information collection requirements are essential components that will protect employees from occupational exposure. The information will be used by employers and employees to implement the protection

required by the standard. OSHA compliance officers will use some of the information in their enforcement of the standard.

Respondents: The respondents are employers whose employees may have occupational exposure in the following settings: hospitals; long-term care facilities for the elderly; correctional facilities and other facilities that house inmates or detainees; hospices; shelters for the homeless; facilities that offer treatment for drug abuse; facilities where high hazard procedures are performed; and laboratories that handle specimens that may contain *M. tuberculosis* or process or maintain the resulting cultures, or perform related activity that may result in the aerosolization of *M. tuberculosis.*

Also, occupational exposure occurring during the provision of social work, social welfare services, teaching, law enforcement or legal services would be covered if the services are provided in the work settings previously mentioned, or in residences, to individuals who are in AFB isolation or are segregated or otherwise confined due to having suspected or confirmed infectious TB. Respondents also include employers whose employees are occupationally exposed during the provision of emergency medical services, home health care and home-based hospice care. Approximately 101,875 employers will be responding to the standard.

Total Estimated Cost: First year $62,972,210; Recurring years $53,691,915.

SUMMARY OF THE COLLECTION OF INFORMATION

Information collection requirement	Number of responses	Frequency of response	Average time per response[1]	Total burden (hours)
Exposure Control Plan:				
(c)(2)(i)	101,875	All Affected Employers to Develop Plan.	• 24 hours per Hospital • 8 hours per Facility for all Other Industries	906,980
(c)(2)(vii)(B)	101,875	Annual Reviews and Updates for All Affected Employers.	• 8 hours per Hospital • 2 hours per Facility for all Other Industries	238,243
Respiratory Protection:				
(f)(2)	82,138	All Employers not Qualified for Appendix A Program to Develop Program.	• 8 hours per Hospital • 4 hours per Facility for all Other Industries	335,323
(f)(5), Appendix B	2,207,580	Initially, for all employees assigned respirators.	• 30 minutes per employee	551,962
	22,078	Annual refit tests for 1% of population assigned respirators.	• 30 minutes per employee	5,520
(f)(8)	82,138	Annual Evaluation of Program for All Affected Employers not Qualified for Appendix A Program.	• 2 hours per Hospital • 1 hour per Facility for all Other Industries	83,831
Medical Surveillance:				
• Medical History (g)(3)(i)(A)	1,831,724	Initially for All Affected Employees	• 1 hour per Hospital Employee (inc. LHCP time). • 1 hour per Employee in all Other Industries (inc. travel time)	1,831,724
	1,595,432	Annually for All Affected Employees in Facilities not Qualified for Appendix A.	• 1 hour per Hospital Employee (inc. LHCP time). • 1 hour per Employee in all Other Industries (inc. travel time)	1,595,432
	47,953	Initially, for New Employees	• 1 hour per Hospital Employee (inc. LHCP time). • 1 hour per Employee in all Other Industries (inc. travel time)	47,953
• Medical Examination (inc. History and Physical) (g)(3)(i)(B)–(D).	47,863	Annually, 3% of Controlled Population at Risk estimated to request exam as a result of having signs or symptoms of TB; have a TST conversion; or indicated as a result of an exposure incident.	• 2 hours per Hospital Employee in Facilities not Qualified for Appendix A (inc. LHCP time). • 1½ hour per Employee in All Other Industries (inc. travel time)	72,518
• Tuberculin Skin Tests				
Initial 2-Step TST (g)(3)(i)(A)	474,627	Initially, for Entire Controlled Population at Risk.	• 1½ hours per Hospital Employee (inc. LHCP time). • 2¼ hour per Employee in All Other Industries (inc. travel time)	1,026,377
Exposure Incident (g)(3)(i)(C).	8,268	Annually, 2% of Controlled Population at Risk in Facilities Qualified for Appendix A.	• 1½ hours per Hospital Employee (inc. LHCP time). • 2¼ hour per Employee in All Other Industries (inc. travel time)	17,879
Pre-Exit (g)(3)(i)(E)	76,257	Annually for Employment Turnover	• 1 hour for each Hospital Employee (inc. LHCP time). • 1½ hour per Employee in All Other Industries (inc. travel time)	110,504
Prior to Initial Assignment	76,257	All New Employees with Occupational Exposure.	• 1½ hour per Hospital Employee (inc. LHCP time).	165,756

SUMMARY OF THE COLLECTION OF INFORMATION—Continued

Information collection requirement	Number of responses	Frequency of response	Average time per response[1]	Total burden (hours)
Annual (g)(3)(ii)(A)	413,400	All employees in facilities not qualified for Appendix A.	• ½ hour per Hospital Employee (inc. LHCP time). • 45 minutes per Employee in all Other Industries (inc. travel time)	297,991
Additional 6-month TST (g)(3)(iii).	131,367	All employees who: • Enter an AFB isolation room or area • Perform or are present during the performance of high-hazard procedures • Transport or are present during the transport of an individual with suspected or confirmed infectious TB in an enclosed vehicle • Work in an intake area in facilities where 6 or more confirmed TB cases have been encountered in the past 12 mos	• 1 hour per Hospital Employee (inc. LHCP time). • 1½ hour for each Employee in All Other Industries (inc. travel time)	171,314
• Information Provided to Licenced Health Care Professional (LHCP) (g)(6)(I).	1,965,967	Information for each affected establishment to provide a copy of the rule, and for information on each employee with a respirator.	• 10 minutes per employee	327,661
	558,549	Information for each new employee assigned a respirator.	• 10 minutes per employee	93,091
	64,692	Information surrounding exposure incidents (2% of controlled population at risk).	• 10 minutes per employee	10,782
• LHCP Written Opinion (g)(7) ..	2,745,188	Initially, for each medical procedure performed.	• 5 minutes per written opinion	228,766
	2,034,269	Annually, for each medical procedure performed.	• 5 minutes per written opinion	169,522
Training:				
(h)(3)(ii)(B)	202,066	Number of training sessions in first year.	• 2 hours for employees required to wear respirators. • 1 hour for employees with occupational exposure who are not assigned respirators • Assumes 20 employees per session	237,829
(h)(3)(ii)(A)	106,258	Number of training sessions for new employees entering affected occupations for the first time + number of training sessions for employees staying in affected occupations, but starting new jobs.	• For new employees: ..... 2 hours for employees required to wear respirators 1 hour for employees with occupational exposure who are not assigned respirators ½ hours for employees required to wear respirators 15 minutes for employees with occupational exposure who are not assigned respirators	50,193
(h)(3)(ii)(C)	154,966	Recurring number of training sessions.	• For 25% of exposed employees unable to demonstrate competence:. 1 hour for employees required to wear respirators ½ hour for employees with occupational exposure who are not assigned respirators • For 75% of exposed employees able to demonstrate competence • Assumes 20 employees per session	57,313
Recordkeeping:				
Medical (I)(1)(I)	3,713,645	Initially, to create a medical record for each affected employee.	• 10 minutes to set up each record	631,320
	1,358,800	Create medical records for each new employee with occupational exposure.	• 10 minutes to set up each record	230,996
	2,447,669	Annually, for each medical procedure performed.	• 5 minutes to update each record	195,814

SUMMARY OF THE COLLECTION OF INFORMATION—Continued

Information collection requirement	Number of responses	Frequency of response	Average time per response[1]	Total burden (hours)
Training (I)(3)(I)	264,451	Initially, to create records for each training session.	• 10 minutes to create each training record.	44,957
	217,351	Annually, to reflect recurring training sessions and initial training for new employees.	• 10 minutes to create each training record.	36,950
Engineering controls (I)(4)(I)	24,761	Annually, for each engineering control.	• 5 minutes per record	3,962
Availability (I)(5)	2,037	Annually, for 2% of affected employers.	• 5 minutes per employer	163
Transfer to NIOSH	1	Annually, for estimated 1 employer per year to transfer records.	• 1 hour per employer	1
Totals.				
• First-Year				7,098,011
• Recurring				3,655,728

[1] Estimates represent average burden hours per response. The actual burden hours per response will vary depending on factors such as the size of the facility, current practices at the facility, and whether the facility transfers or admits individuals with suspected or confirmed infectious TB.

Note: Estimates take into account baseline compliance with the proposed requirements.

The Agency has submitted a copy of the information collection request to OMB for its review and approval. Interested parties are requested to send comments regarding this information collection to the Office of Information and Regulatory Affairs, Attn. OSHA Desk Officer, OMB New Executive Office Building, 725 17th Street NW, Room 10235, Washington DC 20503.

Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget approval of the final information collection request: they will also become a matter of public record.

Copies of the referenced information collection request are available for inspection and copying in the OSHA Docket Office and will be mailed immediately to any person who request copies by telephoning Todd Owen at (202) 219–7075. For electronic copies of the Tuberculosis information collection request, contact the Labor News Bulletin Board (202) 219–4784, or OSHA web page on the Internet at http://www.osha.gov/. Copies of the information collection requests are also available at the OMB docket office.

C. Federalism

This standard has been reviewed in accordance with Executive Order 12612, 52 FR 41685 (October 30, 1987), regarding Federalism. This Order requires that agencies, to the extent possible, refrain from limiting State policy options, consult with States prior to taking any actions that would restrict State policy options, and take such actions only when there is clear constitutional authority and the presence of a problem of national scope. The Order provides for preemption of State law only if there is a clear Congressional intent for the Agency to do so. Any such preemption is to be limited to the extent possible.

Throughout the development of this proposed standard, OSHA has sought and received assistance from state representatives. Representatives of state departments of health and labor and industries have helped direct OSHA to pertinent information and studies on TB and have submitted drafts of state standards relevant to TB. In addition, representatives of state occupational safety and health departments participated in the review of the draft standard by OSHA field offices and in OSHA's TB Stakeholder meetings, where the requirements of the proposed standard were presented and information was collected from employers, employees, and their representatives on what was being done to prevent occupational exposure to TB in the various worksites and how an OSHA standard for TB could further reduce the exposures.

Section 18 of the Occupational Safety and Health Act (OSH Act), expresses Congress' clear intent to preempt State laws with respect to which Federal OSHA has promulgated occupational safety or health standards. Under the OSH Act a State can avoid preemption only if it submits, and obtains Federal approval of, a plan for the development of such standards and their enforcement. Occupational safety and health standards developed by such State-Plan states must, among other things, be at least as effective in providing safe and healthful employment and places of employment as the Federal standards.

The proposed tuberculosis standard is drafted so that employees in every State will be protected by general, performance-oriented standards. To the extent that there are State or regional peculiarities, States with occupational safety and health plans approved under Section 18 of the OSH Act would be able to develop their own State standards to deal with any special problems. Moreover, the performance nature of this standard, of and by itself, allows for flexibility by States and employers to provide as much safety as possible using varying methods consonant with conditions in each State.

There is a clear national problem related to occupational safety and health for employees exposed to *M. tuberculosis*. Approximately 6.5% of the U.S. adult population is infected (i.e., carrying the tuberculosis bacillus, not manifesting active disease), and although the prevalence of TB infection and disease varies throughout the country, TB disease has been reported in every state. Political and geographic boundaries do not contain infection and disease spread. The U.S. population is mobile, moving freely from place to place for business and pleasure. Immigrants, a group whose members are known to have a high prevalence of TB, settle throughout the country. While there are counties that do not report cases in a given year, the counties change from year to year along with the number of cases reported. In addition, reports do not always reflect all the locations where exposure incidents can occur; infectious TB cases are often transferred from their site of diagnosis to a distant location for treatment and reported as a TB case only in the county

where treatment is administered. Finally, underreporting may occur because some individuals with infectious TB, in particular the homeless and clients of drug abuse facilities, do not avail themselves of further diagnosis and treatment. TB infection and disease is truly national in scope.

Those States which have elected to participate under Section 18 of the OSH Act would not be preempted by this regulation and would be able to deal with special, local conditions within the framework provided by this performance-oriented standard while ensuring that their standards are at least as effective as the Federal standard.

D. State Plans

The 23 States and 2 territories with their own OSHA-approved occupational safety and health plans must adopt a comparable standard within 6 months after the publication of a final standard for occupational exposure to tuberculosis or amend their existing standard if it is not ''at least as effective'' as the final Federal standard. OSHA anticipates that this standard will have a substantial impact on state and local employees. The states and territories with occupational safety and health state plans are: Alaska, Arizona, California, Connecticut, Hawaii, Indiana, Iowa, Kentucky, Maryland, Michigan, Minnesota, Nevada, New Mexico, New York, North Carolina, Oregon, Puerto Rico, South Carolina, Tennessee, Utah, Vermont, Virginia, the Virgin Islands, Washington, and Wyoming. (In Connecticut and New York, the plan covers only State and local government employees). Until such time as a State standard is promulgated, Federal OSHA will provide interim enforcement assistance, as appropriate.

II. Pertinent Legal Authority

The purpose of the Occupational Safety and Health Act, 29 U.S.C. 651 *et seq.* (''the Act'') is ''to assure so far as possible every working man and woman in the nation safe and healthful working conditions and to preserve our human resources.'' 29 U.S.C. § 651(b). To achieve this goal Congress authorized the Secretary of Labor to promulgate and enforce occupational safety and health standards. 29 U.S.C. §§ 655(a) (authorizing summary adoption of existing consensus and federal standards within two years of Act's enactment), 655(b) (authorizing promulgation of standards pursuant to notice and comment), 654(b) (requiring employers to comply with OSHA standards).

A safety or health standard is a standard ''which requires conditions, or the adoption or use of one or more practices, means, methods, operations, or processes, reasonably necessary or appropriate to provide safe or healthful employment or places of employment.'' 29 U.S.C. § 652(8).

A standard is reasonably necessary or appropriate within the meaning of Section 652(8) if it substantially reduces or eliminates significant risk, and is economically feasible, technologically feasible, cost effective, consistent with prior Agency action or supported by a reasoned justification for departing from prior Agency actions, supported by substantial evidence, and is better able to effectuate the Act's purposes than any national consensus standard it supersedes. See 58 Fed. Reg. 16612—16616 (March 30, 1993).

OSHA has generally considered, at a minimum, a fatality risk of 1/1000 over a 45-year working lifetime to be a significant health risk. See the Benzene standard, *Industrial Union Dep't* v. *American Petroleum Institute*, 448 U.S. 607, 646 (1980); the Asbestos standard, *International Union, UAW* v. *Pendergrass*, 878 F.2d 389, 393 (D.C. Cir. 1989).

A standard is technologically feasible if the protective measures it requires already exist, can be brought into existence with available technology, or can be created with technology that can reasonably be expected to be developed. *American Textile Mfrs. Institute* v. *OSHA*, 452 U.S. 490, 513 (1981) (''*ATMI*''), *American Iron and Steel Institute* v. *OSHA*, 939 F.2d 975, 980 (D.C. Cir. 1991)(''*AISI*'').

A standard is economically feasible if industry can absorb or pass on the costs of compliance without threatening its long-term profitability or competitive structure. See *ATMI*, 452 U.S. at 530 n. 55; *AISI*, 939 F.2d at 980.

A standard is cost effective if the protective measures it requires are the least costly of the available alternatives that achieve the same level of protection. *ATMI*, 453 U.S. at 514 n. 32; *International Union, UAW* v. *OSHA*, 37 F.3d 665, 668 (D.C. Cir. 1994) (''*LOTO III*'').

All standards must be highly protective. See 58 FR 16614—16615; *LOTO III*, 37 F.3d at 669. However, health standards must also meet the ''feasibility mandate'' of Section 6(b)(7) of the Act, 29 U.S.C. § 655(b)(5). Section 6(b)(5) requires OSHA to select ''the most protective standard consistent with feasibility'' that is needed to reduce significant risk when regulating health hazards. *ATMI*, 452 U.S. at 509.

Section 6(b)(5) also directs OSHA to base health standards on ''the best available evidence,'' including research, demonstrations, and experiments. 29 U.S.C. § 655(b)(5). OSHA shall consider ''in addition to the attainment of the highest degree of health and safety protection * * * the latest scientific data * * * feasibility and experience gained under this and other health and safety laws.'' *Id*.

Section 6(b)(7) authorizes OSHA to include among a standard's requirements labeling, monitoring, medical testing and other information gathering and transmittal provisions. 29 U.S.C. § 655(b)(7).

Finally, whenever practical, standards shall ''be expressed in terms of objective criteria and of the performance desired.'' *Id*.

III. Events Leading to the Proposed Standard

Tuberculosis (TB) is a contagious disease caused by the bacterium *Mycobacterium tuberculosis (M. tuberculosis)*. Infection is usually acquired by the inhalation of airborne particles carrying the bacterium. These airborne particles, called droplet nuclei, can be generated when persons with infectious pulmonary or laryngeal TB cough, sneeze, or speak. TB has long been considered an occupational hazard in the health care setting. However, it is inhalation exposure to aerosolized *M. tuberculosis* and not some other factor unique to the health care setting that places workers at risk of infection. Thus, any work setting where employees can reasonably be anticipated to encounter individuals with infectious TB also contains the occupational hazard of TB infection.

On December 21, 1992, the Labor Coalition to Fight TB in the Workplace (the Coalition) requested the Agency to issue nationwide enforcement guidelines to protect workers against exposure to TB in health care, criminal justice, and other high risk settings and to issue a Joint Advisory Notice on TB in conjunction with the Centers for Disease Control and Prevention (CDC) (Ex. 2). This petition was signed by the presidents of the Service Employees International Union (SEIU), the American Federation of State, County, and Municipal Employees (AFSCME), and the American Federation of Teachers (AFT), and was endorsed by 9 other unions. The petition included a list of provisions that the petitioners felt should be included in the guidelines, ranging from a written control plan and medical surveillance to anti-discrimination language and medical removal protection.

Eight months later, on August 25, 1993, the Coalition petitioned OSHA to initiate rulemaking for a permanent standard issued under § 655(b) of the Act to protect workers from occupational transmission of TB (Ex. 1). Citing the recent resurgence of TB and the emergence and increasing rate of new cases of multidrug-resistant TB (MDR–TB), the petitioners stressed the need for a substance-specific standard to address the hazards associated with occupational exposures to TB. The petitioners contended that the non-mandatory CDC TB Guidelines do not provide adequate protection because they are not fully or rigorously implemented in most workplaces. They also stated that in every outbreak of TB investigated by CDC, noncompliance with the Guidelines was evident.

In addition to a permanent standard, the petitioners also requested that OSHA immediately issue the nationwide enforcement guidelines that the Coalition had previously requested, and that OSHA promulgate an Emergency Temporary Standard (ETS) as an interim measure. The Coalition requested that the standard be applicable to all work settings where employees can reasonably anticipate contact with infectious TB. The petition included a discussion on occupational risk that included both the traditional high-risk occupations and other occupations such as sheet metal workers, postal workers, airline employees, teachers, and office workers.

Like the request for nationwide enforcement guidelines, the petition contained provisions that the petitioners requested be included in the standard. Examples include a facility hazard assessment and written exposure control plan, engineering and work practice controls, respiratory protection, medical surveillance (e.g., tuberculin skin testing) and counseling, post-exposure management, outbreak management, training, and recordkeeping.

On October 8, 1993, OSHA issued nationwide enforcement procedures for occupational exposure to TB. The compliance document contained the enforcement procedures that the Agency could and would use in certain work settings for protecting workers with occupational exposure to TB. In the compliance procedures, the Agency noted that although OSHA has no standard designed specifically to reduce occupational exposure to TB, the Agency has existing standards that apply to this hazard. For example, 29 CFR 1910.134 requires employers to provide respiratory protection equipment and 29 CFR 1910.145(f) requires accident prevention tags to warn of biological hazards. In addition, section 5(a)(1), the General Duty Clause of the Act, requires that each employer:

> * * * furnish to each of his employees employment and a place of employment which are free from recognized hazards that are causing or are likely to cause death or serious physical harm to his employees.

On January 26, 1994, in response to their August 25 petition, Secretary of Labor Robert B. Reich informed the petitioners that OSHA was initiating rulemaking on a permanent standard to be issued under Section 6(b)(5) of the Act for occupational exposure to TB (Ex. 1B). At the same time, the petitioner's request for an ETS was denied. The Agency had determined that the available data did not meet the criteria for an ETS as set forth in Section 6(c) of the Act. However, OSHA committed to enforcing existing regulations and Section 5(a)(1) of the Act in certain work settings while preparing this standard.

On October 28, 1994 the CDC issued revised guidelines for preventing the transmission of tuberculosis in health care facilities (Ex. 4B). In addition, in June of 1995, the National Institute for Occupational Safety and Health (NIOSH) published revised certification procedures for non-powered air purifying particulate respirators (Ex. 7–261). As a result of changes in these two documents, OSHA issued revised enforcement policies and procedures relative to TB in February of 1996 (Ex. 7–260).

In October and November of 1995, OSHA held a series of meetings with stakeholder groups representing labor unions, professional organizations, trade associations, state and federal government, representatives of employers, as well as frontline workers from the various sectors anticipated to be covered by the proposed standard. During these meetings, participants provided input relative to the concepts and approaches OSHA was considering for the proposed tuberculosis standard.

In September of 1996, in accordance with the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), a Small Business Advocacy Review Panel was convened to consider the impact of OSHA's draft proposed tuberculosis standard on affected small entities. The panel, comprised of members from the Office of Advocacy of the Small Business Administration (SBA), the Office of Management and Budget (OMB), and OSHA, prepared a report based on the Panel's findings and recommendations with regard to comments on the standard received from small business employers. This report was submitted to the Assistant Secretary for OSHA for its consideration during the development of the standard (Ex. 12). OSHA's proposed standard reflects input generated during both the stakeholder meetings and the SBREFA review process.

Comparison of OSHA's Proposed Standard and CDC's Revised Guidelines

In preparing its proposed standard for TB, OSHA has relied heavily on the expertise of CDC. The Agency has consulted with CDC and has incorporated the basic elements of CDC's revised guidelines for preventing the transmission of *M. tuberculosis* in health care facilities in this proposed standard. Both CDC and OSHA rely on minimizing exposures and consequent transmission by identifying suspected infectious TB individuals and isolating them. The OSHA proposed standard includes the following CDC components: written exposure control plans, procedures for early identification of individuals with suspected or confirmed infectious TB, procedures for initiating isolation of individuals with suspected or confirmed infectious TB or for referring those individuals to facilities with appropriate isolation capabilities, procedures for investigating employee skin test conversions, and education and training for employees. In addition, OSHA has incorporated CDC recommendations for engineering control measures such as the use of negative pressure for AFB isolation rooms or areas, daily monitoring of negative pressure while AFB isolation rooms are in use for TB, HEPA filtration of recirculated air from AFB isolation rooms, and periodic maintenance and monitoring of engineering controls. With regard to respiratory protection, OSHA has adopted CDC's standard performance criteria for the selection of respiratory protection devices appropriate for use against *M. tuberculosis.* And finally, where appropriate, OSHA has attempted to assure that where certain practices are required by OSHA's proposed standard, e.g., tuberculin skin testing and medical management and follow-up of employees who acquire TB infections or active disease, these practices are conducted according to the current recommendations of the CDC. Therefore, OSHA's proposed standard for occupational exposure to TB closely follows CDC's recommended elements for a TB infection control program.

However, there are some minor differences between OSHA's proposed standard and CDC's guidelines that go

beyond the obvious enforcement distinction between a guideline and a standard. These differences are found primarily in the areas of risk assessment, medical surveillance and respiratory protection. Even so, OSHA believes that despite these differences the vast majority of the provisions included in this proposed standard closely track the recommendations of the CDC. The following discussion identifies where these differences occur and describes the extent of these differences and the degree to which they impact on employers' responsibilities under the proposed standard.

Risk Assessment

As a part of its guidelines, CDC recommends that a risk assessment be conducted in all facilities to assess the risk of transmission of *M. tuberculosis* in each facility. This risk assessment is to be conducted using information such as the profile of TB in the community, the number of suspected and confirmed cases of TB among patients and health care workers, results of health care worker tuberculin skin testing (i.e., conversion rates), and observation of TB infection control practices. Using the results of this risk assessment, appropriate infection control interventions can then be selected based on the actual risk in the facility. CDC includes a protocol for conducting this risk assessment in which there are 5 categories of risk: ''minimal'', ''very-low'', ''low'', ''intermediate'', and ''high''. Each category from ''minimal'' to ''high'' has an increasing number of infection control interventions that are recommended for each particular level of risk.

OSHA, however, has chosen a simpler approach and is not requiring employers to conduct such a risk assessment. Consistent with other standards, OSHA has determined that employees in the work settings and employees providing services set forth in the scope section are at risk of occupational exposure to TB. Their employers are required to conduct an exposure assessment to determine which employees have occupational exposure, i.e., reasonably anticipated contact with an individual with suspected or confirmed infectious TB or air that may contain aerosolized *M. tuberculosis.* The standard then specifies the provisions applicable for the employees whom the employer has identified as having occupational exposure. In addition, consistent with its approach in other standards, OSHA does not require that individual risk assessments be conducted by each work setting covered under the standard, as they may be too difficult and burdensome for employers to prepare. Also, many work settings will have too few occupationally exposed employees to do an accurate risk assessment. Finally, conducting the risk assessments in order to determine applicable duties may require a level of expertise some facilities lack, making enforcement burdensome for the Agency.

OSHA realizes, however, that in many work settings, very few individuals with suspected or confirmed infectious TB may be seen and that in many of those work settings, individuals with suspected or confirmed infectious TB will be transferred to other facilities that are better equipped to provide services and care using appropriate TB isolation precautions. Because there is likely to be less risk of transmission of *M. tuberculosis* in those situations, OSHA believes that it is possible to make the standard less burdensome for the employers with these types of work settings while still maintaining worker protection.

For example, an employer who can demonstrate that his or her facility or work setting: (1) Does not admit or provide medical services to individuals stwith suspected or confirmed infectious TB, (2) has not had any individuals with confirmed infectious TB within the work setting within the last 12 months, and (3) is located in a county that, in the past 2 years, has had 0 cases of confirmed infectious TB reported in one year and fewer than 6 cases of confirmed infectious TB reported in the other year, does not have to comply with all provisions of the standard. Such employers would only be responsible for compliance with certain provisions, e.g., a written exposure control plan, a baseline skin test and medical history, medical management and follow-up after exposure incidents, medical removal protection where necessary, employee training, and recordkeeping. These provisions are very similar to the recommendations of the CDC for facilities classified as having ''minimal risk,'' i.e., no TB in the community or in the facility. The only major difference is that CDC does not recommend baseline skin testing. However, CDC does state that baseline skin testing would be advisable so that if an unexpected exposure does occur, conversion could be distinguished from positive skin test results caused by previous exposures.

Medical Surveillance

In the area of medical surveillance, the main differences between OSHA and CDC are related to tuberculin skin testing. OSHA requires baseline skin testing for all employees whom the employer identifies as having occupational exposure. CDC recommends baseline skin testing for all employees with potential exposure except those who work in facilities that fall into CDC's ''minimal risk'' category. However, CDC notes that even for employees in ''minimal risk'' facilities, it may be advisable to perform baseline skin testing so that if unexpected exposures do occur, conversions can be distinguished from positive skin test results caused by previous exposures. Thus, there is little difference between OSHA requirements and CDC recommendations with regard to baseline skin testing.

Relative to periodic skin testing, OSHA requires periodic re-testing for all employees identified as having occupational exposure who have negative skin tests except for the employees of those employers who have no TB in the community and who have not encountered any individuals with confirmed infectious TB in their work settings within the past year. CDC recommends re-testing for employees in the ''low'', ''intermediate'', and ''high'' risk categories. According to the CDC guidelines, periodic re-testing is not necessary for employees in the ''minimal'' risk category or the ''very-low'' risk categories. CDC's periodic skin test recommendations for the ''minimal'' risk category are similar to OSHA's limited program for employers who do not admit or provide medical services to individuals with suspected or confirmed infectious TB, have not encountered any confirmed infectious TB in their work setting, and are located in a county that, in the past 2 years, has reported 0 cases of confirmed infectious TB in one year and fewer than 6 cases in the other year. OSHA is different from the CDC in that employees in a ''very-low risk category'' are required to be periodically retested. However, CDC notes that even in the ''very-low'' risk category, employees who are involved in the initial assessment of individuals in emergency departments and admitting areas may have potential exposure and thus may need periodic re-testing.

Another difference between CDC and OSHA is the frequency of the re-testing. This is primarily due to the fact that OSHA's required frequencies are based on the type of work that employees do that result in exposures whereas CDC's recommendations are based more on evidence of conversions. For example, OSHA requires re-testing every six months for all employees who (1) enter AFB isolation rooms or areas, (2) perform high-hazard procedures, (3)

transport individuals with suspected or confirmed infectious TB in an enclosed vehicle, or (4) work in intake areas where early identification procedures are performed (e.g., emergency departments, admitting areas) in facilities where 6 or more individuals with confirmed infectious TB have been encountered in the past 12 months. For all other employees with occupational exposure, re-testing is required every 12 months. In comparison, CDC recommends re-testing every year for employees in ''low'' risk categories, every 6–12 months for employees in ''intermediate'' risk categories, and every 3 months for employees in ''high'' risk categories. Under CDC recommendations, employees in ''low'' risk categories who enter AFB isolation rooms or areas or employees who transport individuals with suspected or confirmed infectious TB in an enclosed vehicle would be re-tested every 12 months. However, under OSHA requirements, those same employees would be required to be re-tested every six months. Thus, OSHA is more protective than CDC in this case.

OSHA also would require that employees who perform high-hazard procedures or who work in intake areas where early identification procedures are performed in facilities that encounter 6 or more individuals with confirmed infectious TB be re-tested every six months. Under CDC's Guidelines employees in areas in which cough-inducing procedures are performed on individuals who may have active TB are recommended to follow an intermediate risk protocol. Similarly, CDC recommends that an intermediate risk protocol be followed in areas where more than six individuals who may have active TB receive initial assessment and diagnostic evaluation (e.g., ambulatory care, emergency departments, admitting areas). CDC recommends re-testing every 6–12 months for employees in intermediate risk categories. OSHA would require re-testing every 6 months for the two situations above, which is very similar to CDC's recommendation of re-testing every 6–12 months.

CDC is more protective in its recommendations for employees in the ''high'' risk category. These employees are recommended to be re-tested every 3 months. OSHA does not have a requirement for re-testing employees every 3 months. However, after an exposure incident, OSHA requires that a skin test be administered as soon as feasible and again 3 months after the exposure incident, if the first skin test is negative. Since it is possible that an exposure incident(s) could be the type of event that would cause an employee(s) to be included in the ''high'' risk category as defined by CDC, OSHA requirements, to some extent, track the CDC recommendations for a higher frequency of periodic skin testing.

With regard to two-step testing, both OSHA and CDC require or recommend two-step testing at the time baseline skin testing is administered. Also, both OSHA and CDC add that two-step testing is not necessary if the employee has had a documented negative skin test within the last 12 months. CDC is different from OSHA in that its Guidelines imply that two-step testing can be discontinued if there is evidence of a low frequency of boosting in the facility. OSHA's proposed standard does not allow such an exemption, i.e., for each employee who must have a baseline skin test at the time of the initial medical examination, the skin test must include a two-step test unless the employee has a documented negative test within the last 12 months, regardless of the frequency of boosting in the facility. The value of two-step skin testing is that it enables one to distinguish true conversions from boosted reactions. OSHA believes that this is important to know for each employee because if the employee is incorrectly identified as having converted, he or she may needlessly be subjected to preventive therapy that may have toxic side effects of its own. Since it is important to know the true skin test status for each employee, OSHA has preliminarily concluded that it is inappropriate to allow the overall frequency of boosting among employees in a facility to dictate whether any one employee receives two-step testing at the time of his or her baseline testing.

Respiratory Protection

OSHA requirements and CDC recommendations for respiratory protection are very similar. A respirator is a personal protective equipment device worn over the nose and mouth of the employee that filters certain airborne contaminants from the inhaled air. OSHA has adopted CDC's performance criteria for respirators appropriate for use for TB. Also, both OSHA and CDC have similar requirements or recommendations that respirators be worn when entering an isolation room, when performing cough-inducing procedures or aerosol-generating procedures on an individual with suspected or confirmed infectious TB, when repairing or maintaining air systems that may contain aerosolized *M. tuberculosis*, when transporting an individual with suspected or confirmed infectious TB in an enclosed vehicle and when working in a residence where an individual with suspected or confirmed infectious TB is known to be present. However, OSHA also requires that respirators be worn when employees are transporting individuals with suspected or confirmed infectious TB within the facility if those individuals are not masked (e.g., a surgical mask or a valveless respirator). CDC does not have a similar recommendation for respiratory protection while transporting individuals within the facility, but CDC does recommend, and assumes to some extent, that individuals with suspected or confirmed infectious TB are masked whenever they are outside an isolation room. In addition, OSHA requires that respirators be worn when employees work in an area where an unmasked individual with suspected or confirmed infectious TB has been segregated or otherwise confined. For example, this provision would cover employees such as those who work in admitting areas and must attend to unmasked individuals with suspected or confirmed infectious TB while those individuals are awaiting transfer. These types of employees are likely to be found in facilities that would meet CDC's definition of ''minimal'' risk. CDC states that respiratory protection is not necessary for employees in the ''minimal'' risk category. However, again, CDC recommends that if an individual with suspected or confirmed infectious TB is identified in a ''minimal'' risk facility, the individual should be masked while he or she is awaiting transfer to another facility, thus obviating the need for respiratory protection. OSHA, on the other hand, cannot require employers to mask clients or patients in a facility, and the Agency must therefore include provisions for respirator use to protect potentially exposed employees. However, consistent with CDC, OSHA proposes not to require respirators where the employer elects, as a part of his or her own administrative policies, to mask individuals with suspected or confirmed infectious TB. Thus, when individuals with suspected or confirmed infectious TB are masked while they are awaiting transfer to another facility or while they are being transported within the facility, employees would not be required by the standard to wear a respirator.

In some instances, the CDC may be more protective than OSHA with regard to respiratory protection. The CDC states that the facility's risk assessment may identify selected settings where the

estimated risk of transmission of *M. tuberculosis* may be such that a level of respiratory protection exceeding the standard performance criteria is appropriate (e.g., more protective negative pressure respirators, powered air purifying respirators). The examples given of such selected settings are a bronchoscopy performed on an individual suspected of having TB and an autopsy performed on a deceased person suspected of having had active TB at the time of death. OSHA does not have a similar requirement for more protective respiratory protection. Respirators meeting the minimal performance criteria laid out by the standard would be required by OSHA for employees performing all high-hazard procedures, including bronchoscopies and aerosol-generating autopsy procedures.

IV. Health Effects

Introduction

For centuries Tuberculosis (TB) has been responsible for the death of millions of people throughout the world. It was not until 1882, however, that Robert Koch identified a species of bacteria, *Mycobacterium tuberculosis (M. tuberculosis),* as the cause of TB.

TB is a communicable disease that usually affects the lungs. The airborne route is the predominant mode of transmission, a situation created when individuals with infectious TB discharge the bacilli from the lungs when coughing, sneezing, speaking or singing. Some individuals who breathe contaminated air become infected with TB. Most often, the immune system responds to fight the infection. Within a few weeks, the infected lesions become inactive and there is no residual change except for possible lymph node calcifications. These individuals will have a positive skin test result. They will harbor the infection for life. At some time in the future, the infection can progress and can become an active disease, with pulmonary infiltration, cavitation, and fibrosis, possibly causing permanent lung damage and even death. With some exceptions, however, TB is treatable with antimicrobial drugs. If the active TB is treated early, there will be minimal residual lung damage. For this reason, individuals who have a TB exposure incident and develop a TB infection are treated to prevent progression to active TB disease.

With the introduction of antimicrobial drug treatment in the 1940s and the creation of programs in the United States such as the U.S. Public Health Service's Tuberculosis Program, there began a decline in the incidence of active TB cases in the U.S. From 1953, when active cases began to be reported in the U.S., until 1984, the number of annual reported cases declined 74%, from 84,304 (53 per 100,000) to 22,255 (9.4 per 100,000) (Ex. 7–50). However, this steady decline in TB cases did not continue. Instead, from 1985 through 1992, the number of reported TB cases increased 20.1% from 22,201 to 26,673 (10.5 cases per 100,000) (Ex. 6–13).

This resurgence in TB brought to attention a number of problems in the existing TB control programs. The direction of resources to areas with the highest increase in active cases has caused this increase to decline. The number of cases reported for 1995 indicates that the rate of active TB has returned to its 1985 levels. In 1995, a total of 22,813 cases of TB (8.7 per 100,000) was reported to CDC (Ex. 6–34). While this represents a decline in active TB, the 1995 rate is still two and one half times greater than the target case rate of 3.5 per 100,000 for the year 2000 and approximately 87 times the goal of less than one case per million population by the year 2010 proposed by the Advisory Committee on the Elimination of Tuberculosis (Ex. 6–19).

TB continues to be a national problem. Each year, cases of active disease are reported in every state in the Nation and in a substantial majority of counties nationwide. CDC estimated in 1990 that approximately 10 million people were infected with the tuberculosis bacterium and that approximately 90% of the new cases of active disease that arise in the United States come from this already infected group (Ex. 7–52). Given the recent resurgence of TB, it is likely that a new population of individuals has been infected as well. Of great concern are strains of *M. tuberculosis* that have emerged that are resistant to several of the first-line anti-TB drugs normally used to treat TB infection and disease (e.g., isoniazid and rifampin). This drug-resistant form of the disease, referred to as multidrug-resistant TB or MDR–TB, is more often a fatal form of TB due to the difficulty in finding antimicrobial drugs to stop the bacteria's growth and progressive tissue destruction. In addition, individuals with MDR–TB often remain infectious for longer periods of time due to delays in diagnosing resistance patterns and initiating appropriate treatment. This, in turn, increases the risk that infectious individuals will transmit the organism to other persons coming in contact with them.

Most of the decreases in reported cases of TB since 1992 have occurred in areas such as New York City, where resources have been invested to improve or initiate TB control provisions, such as those outlined in OSHA's proposed standard. However, the 1995 statistics show that over the course of four years there is substantial variability in the increases and decreases of cases reported by each state for any given year (Ex. 6–34). In 1995, 15 states reported an increase in the number of TB cases compared with 1994. In addition, a recent study has shown that MDR–TB has spread to patients in Florida and Nevada, and to health care workers in Atlanta, Georgia and Miami, Florida. Moreover, one individual with MDR–TB infected or caused disease in at least 12 people in a nursing home in Denver, Colorado (Ex. 7–259). This study shows very clearly the ability of TB to be spread to different areas of the country. This is to be expected given the mobile nature of today's society and the frequency with which people travel. Immigration also contributes to the incidence of the disease. For example, while the number of active TB cases has decreased among U.S. born persons, the number of foreign born persons reported with TB has increased 63% since 1986, with a 5.4% increase in 1995 (i.e., from 7,627 cases in 1994 to 8,042 cases in 1995). Thirty to fifty percent of these cases were diagnosed 1 to 5 years after the individual enters the U.S. (Ex. 6–34). Thus, tuberculosis continues to be a public health problem throughout the United States.

The following discussion will briefly describe the basic concepts and terminology associated with TB as well as common factors that facilitate its transmission from one individual to another. This discussion will also include a review of studies relating to the occupational transmission of TB.

Background

TB is a contagious disease caused by the bacterium *M. tuberculosis.* Infection is generally acquired by the inhalation of airborne particles carrying the bacterium. These airborne particles, called droplet nuclei, can be generated when persons with pulmonary or laryngeal tuberculosis in the infectious state of the disease cough, sneeze, speak or sing.

In some individuals exposed to droplet nuclei, tuberculosis bacilli enter the lung and establish an infection (Ex. 7–52). Once in the alveoli, the tuberculosis bacilli are taken up by alveolar macrophages and spread throughout the body by the lymphatic system, until the immune response limits further growth (usually a period of two to ten weeks). In most cases the tuberculosis bacilli are contained by the

immune response. Macrophage cells engulf the bacteria, which limits the spread of the bacilli. Initial lesions from infection heal; however, small calcifications called tubercles are formed and may remain a potential site of later reactivation.

Individuals in this state are infected with TB. They will show a positive skin test and they are at risk of developing active TB, a risk they carry throughout their lifetime. In many cases, as described below, preventive therapy is initiated with anti-TB drugs to prevent the progression to active TB disease. These drugs are toxic and may cause adverse effects such as hepatitis. Severe preventive therapy-associated hepatitis cases have necessitated liver transplants and in some cases have resulted in death (Ex. 6–10).

When the bacilli are not contained by the immune system, they continue to grow and invade the tissue, leading to the progressive destruction of the organ involved, which in most cases is the lung, i.e., pulmonary tuberculosis. The inflammatory response caused by the disease produces weakness, fever, chest pain, cough, and, when blood vessels are eroded, bloody sputum. Also, many individuals have drenching night sweats over the upper half of the body several times a week (Ex. 5–80). The extent of disease varies from minimal symptoms of disease to massive involvement with extensive cavitation and debilitating constitutional and respiratory symptoms. Since tuberculosis bacilli are spread throughout the body after the initial infection, other organs may also be infected and disease may occur at sites outside the lung, i.e., extrapulmonary tuberculosis.

There are two general stages of TB, tuberculosis infection and active tuberculosis disease. Individuals with tuberculosis infection and no active disease are not infectious. These tuberculosis infections are asymptomatic or subclinical and are only detected by a positive response to a tuberculin skin test. However, there are some individuals whose immune system is impaired and cannot mount a sufficient response to skin test antigens, i.e., they are anergic. Such individuals may be infected, although they do not show a positive response to the skin test. Individuals with tuberculosis infection and no disease would have negative bacteriologic studies and no clinical or radiographic evidence of tuberculosis disease. However, these individuals are infected for life and are at risk of developing active TB in the future.

Anti-tuberculosis drugs may be used for individuals with TB infection but who do not have active disease. In these cases, the antimicrobials are used as preventive therapy to prevent the onset of active disease. Because of the toxicity associated with the antimicrobials, preventive therapy may not be appropriate for all infected individuals. Various factors are considered to determine whether an infected individual is an appropriate candidate for preventive therapy (e.g., age, immune status, how recently the infection occurred, and other high-risk factors associated with TB) (Ex. 7–52, pg. 17). Isoniazid is currently the only drug that has been well tested in humans for its efficacy as preventive therapy (Ex. 7–50, pg. 61). However, serious side effects may result from isoniazid. A study in New York for the years 1991 to 1993 examined cases of hepatitis induced by isoniazid preventive therapy. In this study, 10 patients undergoing preventive therapy for TB were identified at a transplant center. Eight of these patients had developed hepatitis from isoniazid. Five received a liver transplant; the other three died while awaiting a liver donor. In addition, one of the transplant patients died after transplantation. Thus, preventive therapy may carry considerable risks for infected individuals.

In those cases where isoniazid cannot be tolerated by the patient or where it is suspected that infection resulted from exposure to isoniazid-resistant strains of *M. tuberculosis*, rifampin may be recommended for preventive therapy. Considerations for such alternative drug therapies are made on a case-by-case basis by the health care provider based on the medical and case history of the infected patient. Rifampin has adverse side effects as well. However, preventive therapy using rifampin has not been followed as well as that involving isoniazid and therefore, its side effects are less well characterized.

Individuals with active TB have clinical and/or radiographic evidence of disease. The initial laboratory method for diagnosing TB is the Acid Fast Bacilli (AFB) smear. This is a quick and easy technique in which body fluids, typically sputum samples, from individuals with suspected TB are examined for mycobacteria. However, this type of test only permits a presumptive diagnosis of TB since the test cannot distinguish between tuberculosis mycobacteria and other non-tuberculosis mycobacteria. Chest X-rays may also be used to diagnose active TB; however, some individuals with TB may have X-ray findings that are atypical of those usually associated with TB (e.g., HIV infected individuals). The diagnosis of clinically active TB is most definitively established by the isolation of *M. tuberculosis* in culture. However, it may take three to six weeks or longer from obtaining a culture to getting a result.

Individuals with active TB disease may be infectious, especially if they are untreated or inadequately treated and if the disease is in the lungs. The clinical symptoms of pulmonary TB include loss of appetite, weight loss, fatigue, fever, night sweats, malaise, cough with productive sputum and/or blood, and chest pain. The extent of the disease varies from very minimal symptoms to extensive debilitating constitutional and respiratory symptoms. If untreated, the pulmonary TB follows a chronic and progressive course in which the tissue is progressively destroyed. It has been estimated that approximately 40 to 60% of untreated cases result in death (Exs. 5–80, 7–50, and 7–66). However, even among cured cases of TB, long-term damage can result, including impaired breathing due to lung damage (Ex. 7–50, pg. 31).

Approximately 90% of immunocompetent adults who are infected do not develop active TB disease. However, for 10% of infected immunocompetent adults, either directly after infection or after a latency period of months, years or even decades, the initial infection progresses to clinical illness, that is, active TB (Ex. 4B). The risk of developing active TB is increased for individuals whose immune system is impaired (i.e., immunocompromised). Such individuals include persons undergoing treatment with corticosteroid or immunosuppressive drugs (e.g., persons with organ transplants or persons undergoing chemotherapy for cancer), persons suffering from malnutrition or chronic conditions such as asthma and emphysema, and persons infected with the human immunodeficiency virus (HIV).

The main first-line drugs currently used to treat active TB are isoniazid, rifampin, pyrazinamide, ethambutol and streptomycin. Combinations of these antimicrobials are used to attack the tuberculosis bacilli in the body. Recommended treatment regimens include two or more drugs to which the bacilli are susceptible, because the use of a single drug can lead to the development of bacilli resistant to that drug (Ex. 5–85). Treatment with these first-line drugs involves a two-phase process: an initial bactericidal phase for the quick elimination of the bulk of bacilli from most body sites and a longer-term sterilizing phase for eliminating the remaining bacilli.

Different regimes of drug treatment (i.e., the types of drugs and frequency of administration) are recommended depending on the medical history of the patient involved and the results of drug susceptibility testing. The U.S. Public Health Service has recommended options for the initial therapy and dosage schedules for the treatment of drug-susceptible TB (Ex. 4B). While these antimicrobials are effective in the treatment of active TB, some of these drugs also have toxic potential. Adverse side effects of these drugs include hepatitis, peripheral neuropathy, optic neuritis, ototoxicity and renal toxicity (Ex. 7–93). Thus, patients undergoing TB therapy must also be monitored for drug toxicity that may occur from anti-tuberculosis drugs.

Individuals with active disease who are infectious may need to be hospitalized in order to provide isolation so that they will not infect other individuals. After the initiation of treatment for active TB, improvement of the disease can be measured through clinical observations such as loss of fever, reduction in coughing, increased appetite and weight gain. A reduction in the number of bacilli in sputum smears also indicates improvement. Three consecutive negative sputum smears generally indicate that the individual is no longer infectious. However, decisions about infectiousness are usually determined on a case-by-case basis after taking a number of factors into consideration, such as the presence of cough, the positivity of sputum smears, and the status or response to chemotherapy. Although no longer infectious to other individuals, the individual undergoing treatment still has tuberculosis disease and must continue treatment. Discontinuing or erratically adhering to the treatment regime can allow some of the bacilli to survive such that the individual will be at risk of becoming ill and infectious again (Ex. 7–52, p. 25).

Not all strains of the tuberculosis bacilli are susceptible to all of the antimicrobials used to treat TB. In some instances, drug-resistant forms of *M. tuberculosis* may emerge. Drug resistance may emerge by 1 of 3 mechanisms (Exs. 5–85; 7–50, pp. 44–47). Drug-resistant TB may occur naturally from random mutation processes, i.e., primary resistance. In addition, drug-resistant TB may result due to inadequate or erratic treatment, i.e., acquired resistance. In these cases, erratic or inadequate treatment allows the tuberculosis bacilli to become resistant to one or several of the drugs being used. Finally, drug-resistant TB may result due to the active transmission of drug-resistant TB from an individual already infected with drug-resistant strains of the tuberculosis bacteria, i.e., transmitted resistance. In recent years, drug-resistant forms of TB have emerged that are resistant to two or more of the first-line drugs used to treat TB, such as isoniazid and rifampin, two of the most effective anti-TB drugs. These drug-resistant forms of the disease are referred to as multidrug-resistant TB or MDR–TB. MDR–TB represents a significant form of drug-resistant TB from a public health standpoint, since its resistance to the first-line drugs used for therapy complicates finding adequate therapy regimens that will control the bacilli's growth.

Treatment of drug-resistant TB is determined on a case-by-case basis, using information from the patient's medical history and drug susceptibility testing. The recommended course of treatment will vary depending on the drugs to which the bacilli are susceptible. Compared to conventional TB drug therapy, MDR–TB, in general, requires more complex interventions, longer hospitalization and more extensive laboratory monitoring. The risk of death from such infections is markedly increased. For example, from January 1990 through September 1992, the CDC investigated eight outbreaks of MDR–TB. In these outbreaks, 253 patients were infected, of whom approximately 75% died (Ex. 3–38–A). Many of these were immunocompromised due to infection with HIV. The interval from the time of TB diagnosis to the time of death ranged from 4 to 16 weeks, with a median time of 8 weeks.

Factors Affecting Transmission

A number of factors can influence the likelihood of acquiring a tuberculosis infection: (1) The probability of coming into contact with an individual with infectious TB, (2) the closeness of the contact, (3) the duration of the contact, (4) the number of tuberculosis bacilli in the air, and (5) the susceptibility of the uninfected individual. Several environmental conditions can influence the likelihood of infection. For example, the volume of shared air space, the amount of ventilation, the presence or absence of sunlight, the humidity and the crowded nature of the living quarters. These types of factors will affect the probability of acquiring a tuberculosis infection after being exposed to an individual with infectious TB. MDR–TB is not more contagious than drug-susceptible forms of the disease. However, due to time delays in diagnosing resistance patterns and initiating adequate treatment, individuals with active MDR–TB may remain infectious for longer periods of time. Consequently, the likelihood that they will infect other noninfected individuals is increased.

Once infection occurs, other factors may influence the probability of progressing to the active form of disease. As previously discussed, 10% of immunocompetent adults infected with TB develop active TB. Three to five percent of untreated immunocompetent adults develop active TB within the first year after infection (Ex. 7–50, pg. 30; 7–52). Thus, recently infected individuals have the highest risk of developing active TB. This risk is increased for individuals whose immune system is impaired (e.g., persons being treated with immunosuppressive or glucocorticoid drugs, persons with chronic conditions such as asthma or emphysema or persons infected with the HIV). The probability of developing active disease can also be influenced by other conditions that may alter immune function such as overall decreased general health status, malnutrition, and increasing age.

The resurgence of TB in the United States from 1985 to 1992 has been attributed to a number of interacting factors: (1) The inadequate control of disease in high prevalence areas; (2) the increase in poverty, substance abuse, poor health status and crowded substandard living conditions; and (3) the growing number of inmates, residents of homeless shelters, elderly persons in long-term care facilities, persons with HIV infection and immigrants from countries with a high prevalence of TB infection (Ex. 7–50). This increase has begun to decline, with the 1995 case levels approaching the 1985 levels. However, a main reason for this decrease is the implementation of TB control measures, like those proposed in this standard, in selected areas of the country such as New York City. OSHA believes that implementation of such measures is necessary to prevent a resurgent peak such as that observed from 1985 to 1992 and to realize the goal set out by the National Advisory Committee for the Elimination of Tuberculosis. The following discussion describes some of the health effects data related to occupational exposure to TB and illustrates how the presence of TB control measures influences TB infection and disease.

Occupational Exposure

Exposure to TB in the health care setting has long been considered an occupational hazard. With the steady

decline in reported TB cases from 1953 to 1985, some of the concern for occupational exposure and transmission also declined. However, from 1985 to 1992 the number of reported cases of TB increased. In addition, in recent years, several outbreaks of TB among both patients and staff in hospital settings have been reported to the CDC. These outbreaks have been attributed to several factors: (1) Delayed recognition of active TB cases, (2) delayed drug susceptibility testing, (3) inadequate isolation of individuals with active TB (e.g., lack of negative pressure ventilation in isolation rooms, recirculation of unfiltered air, and allowing infectious patients to freely move in and out of isolation rooms), and (4) performance of high-risk procedures on infectious individuals under uncontrolled conditions (Ex. 7–50). In addition to hospitals, outbreaks of TB have also been reported among the patients, clients, residents and staff of correctional facilities, drug treatment centers, homeless shelters and long-term health care facilities for the elderly. The factors contributing to the outbreaks in these other occupational settings are very similar to those factors contributing to the outbreaks in hospital settings (i.e., delayed recognition of TB cases and poor/inadequate ventilation for isolation areas).

The following is a discussion of some of the studies that have examined occupational transmission of TB. A large proportion of the available information comes from exposures occurring in hospitals, in part because this occupational setting has been recognized for many years as an area of concern with regards to the transmission of TB. However, in more recent years this concern has spread to other occupational settings which share factors identified in the hospital setting as contributing to the transmission of disease. The following sections will include a discussion of some of the historical data from the hospital setting, as well as the more recent data that have been developed in hospitals and other occupational settings where the transmission of TB has occurred as a result of the recent resurgences in the number of active TB cases.

Hospitals—Prior to 1985

Even prior to the recent resurgence of TB in the general population, studies have shown an increased risk of transmission of TB to health care workers exposed to individuals with infectious TB. These studies clearly demonstrate that in the absence of appropriate TB control measures (e.g., lack of early identification procedures, lack of appropriate engineering controls), employees exposed to individuals with infectious TB have become infected and in some cases have developed active disease.

In 1979, Barrett-Connor (Ex. 5–11) examined the incidence of TB among currently practicing physicians who graduated from California medical schools from approximately 1950 to 1979. Through mailed questionnaires, physicians were asked to provide information that included their year of graduation from medical school, BCG vaccination history, history of active TB, results of their tuberculin skin testing, and the number of patients they were exposed to with active TB within the past year. They were also asked to classify themselves as tuberculin positive or negative and to indicate the year of the last negative and first positive tuberculin test.

Of the 6425 questionnaires mailed out, 4140 responses were received from currently practicing physicians. Twelve percent of the physicians had received the BCG vaccine. Sixty-one percent of the unimmunized physicians, who also had no history of active tuberculosis, considered themselves to be tuberculin negative. A total of 1542 (42%) reported themselves as having a positive response to the tuberculin skin test, with approximately 44 percent of those tuberculosis infections occurring before entering medical school. Of those infections occurring before entering medical school, approximately eight percent were reported as having been a result of contact following work experience in the hospital prior to entering medical school. For those physicians infected either during or after medical school, the sources of infection were reported as occurring as a result of a known patient contact (45.1%), an unknown contact (41.5%) and a non-patient contact (13.4%). In some cases, the nonpatient contact was reported as another physician or another hospital employee. Approximately one in ten of the physicians infected after entry into medical school developed active TB disease.

The authors also examined the incidence of infection, measured as the conversion rates in those remaining negative at the end of different time intervals (e.g., the last three years of medical school and five to 10 years after graduation). This examination indicated that from 1950 to 1975, there was a 78% decrease in tuberculin conversion rates despite the expanding pool of susceptible medical students (i.e., an increasing number of medical students who were tuberculin negative). Yet despite this overall decrease in infection rates over a 25 year period, tuberculin conversion rates among recent graduates exceeded 1% per year and age-specific infection rates among all the physicians studied were more than twice that of the U.S. population at comparable ages. The authors did not obtain information from the physicians on what type of infection control measures were being used in the facilities where they acquired their infections.

A similar analysis by Geisleler et al. (Ex. 7–46) evaluated the occurrence of active tuberculosis among physicians graduating from the University of Illinois medical school between the years 1938 and 1981. This study, also conducted by questionnaire, reported that among 4575 physicians questioned, there were 66 cases of active TB, of which 23% occurred after 1970. Sixty-six percent of the cases occurred within 6 years of graduation. In addition, the authors reported that in most years the incidence of TB was greater among these physicians than the general population.

Weiss (Ex. 7–45) examined tuberculosis among student health nurses in a Philadelphia hospital. From 1935 to 1939, before the introduction of anti-TB drugs and the beginning of the general decline of TB in the United States, 100% conversion rates were observed among those students who were initially tuberculin negative. For example, of 643 students admitted, 43% were tuberculin negative. At the end of only 4 months, 48% were tuberculin positive. At the end of 1 year, 85.9% were tuberculin positive and by the end of the third year 100% were positive. Of those students who converted during their student nursing tenure, approximately 5 percent developed active TB disease.

A decline in the rate of infection was observed over the next 36 years among student nurses at this hospital. The rates of infection were followed for ten classes of student nurses from 1962 to 1971. The students had little contact with patients during their first year but spent 4 weeks of their second year of training on the tuberculosis wards. Among those students initially tuberculin negative, the average conversion rate was 4.2% over the nine year period, ranging from 0 to 10.2%. Of the students who converted, 0.6% developed active TB disease. The authors attributed the decreases in conversion rates to not only the general decrease in TB disease in the community, but also to the increased efficiency of surveillance of patients entering the hospital for the early identification of potential cases of TB and the increased efficiency of isolation

for TB patients. Despite the dramatic decreases in conversion rates among these student nurses, conversion rates were observed at levels as high as 10% for a given year, indicating that while the infection rates had decreased substantially since 1939, there still remained a significant amount of occupational transmission of TB in 1971. Moreover, this study shows that short term exposure, i.e., 4 weeks, is capable of infecting hospital employees.

Similar rates of conversion among hospital employees initially tuberculin negative were observed in a 1977 study by Ruben et al. (Ex. 7–43) which analyzed the results of a tuberculin skin testing program 31 months after its inception at a university hospital in Pittsburgh. Of 626 employees who were tested twice with the tuberculin skin test, 28 (4.5%) converted from negative to positive. The employees were classified as either having a ''presumed high degree of patient exposure'' or a ''presumed low degree of patient exposure''. Employees presumed to have high patient exposure included nurses, X-ray and isotope laboratory personnel and central escort workers. Employees presumed to have low exposure included secretaries, persons in housekeeping and dietary work, and business office, laundry and central supply personnel. The rates of conversion for employees with presumed high exposure (6%) and for employees with presumed low exposure (8%) were not significantly different. However, this study excluded physicians and medical and nursing students. These groups of employees would also presumably have had high exposure to patients since they are often the hospital staff most directly involved in administering patient care. Had these employees been included the number of conversions among employees with presumably high exposure may have been significantly increased.

The study was not designed to determine the source of exposure for any of the employees who converted. However, the authors suggested that the high level of conversions among those employees with presumed low exposure to patients may have resulted from exposures at home. A majority of this group was comprised of housekeeping staff who were of low socio-economic status. The authors also suggested that unrecognized cases of tuberculosis may be playing an important role in the occupational transmission of TB in the hospital.

Unrecognized cases of TB have been shown to play a significant role in the outbreak of TB in a general hospital. In 1972, Ehrenkranz and Kicklighter (Ex. 5–15) reported a case study in which 23 employees converted after exposure to a patient with an undetected case of tuberculosis bronchopneumonia. In this study, the source case was an individual who was admitted to the emergency room with pulmonary edema. Upper lobe changes of the lung were noted in the chest X-ray, and TB was mentioned as a possible cause. However, no sputum cytology was conducted. The patient spent 3 hours in the emergency room, 57 hours in a private room and another 67 hours in intensive care until his death. Treatment of the patient included intubation with an endotracheal tube and vigorous nasotracheal suctioning. It was only upon microscopic examination of tissue samples of the lung and lymph nodes after the autopsy of the patient that tuberculosis mycobacteria were detected.

Employees who worked in the emergency room, the intensive care unit and on the floor of the private room (NW 3) and who were also tuberculin negative before the admission of the patient, were retested to detect possible conversion. In addition, 21 initially tuberculin negative employees on an adjacent floor (NW 2) were also retested. Of the 121 employees tested, 24 were identified as having converted to positive status (21 working on NW 3, 2 working in the intensive care unit and 1 working on NW 2). No conversions were observed among those working in the emergency room.

The employees who were retested were classified as either having close contact (e.g., providing direct care), little contact (e.g., more distant contact), unknown contact (e.g., no record or recollection of contact) or indirect contact (e.g., in the same room a day or two after the patient's stay). Conversions occurred in 50% (13 of 26) of those employees with close contact, 18.5% (6 of 33) of those with little contact, 21.4% (3 of 14) of those with unknown contact and 3.7% (1 of 29) of those with indirect contact.

While the majority of conversions seems to have occurred in those employees on NW 3 who had close or little contact, there also were employees with more distant contact who were infected. An analysis of the ventilation of NW 3 indicated that the central air conditioning recycled 70% of the air with no high efficiency filter and no record of balancing the air conditioning system, thus allowing the air from the patients' rooms to mix with and return to the central corridor air. In addition, smoke tube tests detected direct air flow from the patients' rooms to the hall corridor. Perhaps the more important factor was that the patient was not diagnosed with infectious TB until after his death, by which time he had already infected 24 employees.

These earlier studies illustrate that despite the decrease in TB morbidity since the advent of anti-tuberculosis drugs in the 1940's, occupational transmission of TB continues to be a problem. In addition, while many improvements have been made in infection control procedures for TB in hospitals, evidence of occupational transmission of TB continues to be reported.

Hospitals—1985 to Present

As discussed above, the transmission of TB has been well established as an occupational hazard in the hospital setting. Many improvements were made in infection control practices. However, the resurgence in TB from 1985 to 1992 has brought to attention the fact that many TB control measures have not been implemented or have been inadequately applied. These studies demonstrate that TB continues to be an occupational hazard in the hospital setting. In addition, similar to the earlier studies, the more recent data show that the lack of early identification procedures and the lack of appropriate ventilation, performance of high-hazard procedures under uncontrolled conditions and the lack of appropriate respiratory protection have resulted in the infection of employees and in some cases the development of active disease. The more current outbreaks are even more troubling due to the emergence of multidrug-resistant forms of TB disease, which in some cases have resulted in fatality rates approaching 75%.

In a 1985 study, Chan and Tabak (Ex. 7–3) investigated the risk of TB infection among physicians in training at a Miami hospital. In this study a survey was conducted among 665 physicians in training who were in their first four years of postgraduate training. Only 404 responded to the survey, of which 13 were illegible. Another 72 were excluded because they had received the BCG vaccination. Of the remaining 319 physicians, 55 were tuberculin positive.

Of the 279 who were tuberculin negative at the beginning of their post graduate training, 15 were excluded because they had more than four years of training and 43 were excluded because they had not had repeat skin tests. Of the 221 remaining available for evaluation, 15 converted to positive tuberculin status, of which two developed active disease.

The overall conversion rate for these physicians was 6.79%. In addition, the

authors observed a positive correlation between the rate of conversion and the duration of postgraduate training. The conversion rate increased with the duration of training, beginning with a cumulative percentage of conversion of 2.06% in the first year, 8.62% in the 2nd year, 11.11% in the third year and 14.29% in the fourth year, resulting in a linear conversion rate of 3.96% per year. As noted by the authors, this linear increase suggests the hospital environment as the source of the infection. In addition, the prevalence rate of conversions in the hospital (17.24%) was much higher than would have been expected in the community for individuals of the same age.

The authors suggested that these high rates of conversion may have been a result of the fact that the hospital in this study encounters 5 to 10 times more active TB cases than most other urban hospitals. In addition, the physicians in training also are expected to be the first in line to perform physical evaluations and evaluate body fluids and secretions. While the authors did not go into detail about what, if any, TB infection control precautions were taken by these physicians in training, they did note that the evaluation of body fluids and secretions was often done in poorly ventilated and ill-equipped laboratories.

Increased rates of conversion were observed among employees in a New Orleans hospital in a 1986 study by Ktsanes et al. (Ex. 7–6). Similar to Miami, New Orleans also has a high rate of TB in the community. This study examined the skin test conversions among a cohort of 550 new employees who were followed for five years after assignment to the adult inpatient services. Of these 550 employees who were initially tuberculin negative, 17 converted to positive status over the five-year study period, resulting in an overall five-year cumulative conversion probability of 5.2%.

Regression analyses were done to examine potential contributing factors. Factors examined in the regression model included race, job, age at employment, and department. Only race (i.e., black vs. white employees) and job (i.e., nursing vs. other jobs) were found to be associated with skin test conversion. To further examine the potential job effect, conversions among blacks in nursing and blacks in other jobs were compared. Overall, the cumulative probability of converting was higher among blacks in nursing, suggesting that the acquired infections resulted from employment at the hospital rather than from the community at large. The authors thus concluded that there is an increased risk of occupational transmission of TB in TB-prevalent areas for those in close patient contact jobs.

In 1989, Haley *et al.* (Ex. 5–16) conducted a case study of a TB outbreak among emergency room personnel at a Texas hospital. In this study, a 70 year old male diagnosed with pulmonary TB and undergoing treatment was diverted, due to respiratory arrest, to Parkland Memorial Hospital while in route to another hospital. The man was admitted to the emergency room for approximately 4 hours until he was stabilized. Afterwards, the patient was placed in an intensive care unit, where he remained for 2 months until his death.

Six cases of active TB developed among emergency room employees after exposure to the TB patient, i.e., the index case. Five of these were among nurses who recalled contact with the index patient and a sixth case was an orderly who may have been infected from one of the employee TB cases. In addition, a physician exposed while administering treatment in the intensive care unit also developed active disease.

Skin test conversions were evaluated for the 153 employees of the emergency room. Of 112 previously negative employees, 16 had positive skin tests, including 5 nurses diagnosed with active TB. Fifteen of the conversions were a result of exposure to the index case. Skin tests were also evaluated for physicians in the intensive care unit. Of 21 resident physicians, two of whom had intubated the index patient, five had newly positive reactions to the tuberculin skin tests. One of the remaining three residents later developed active disease.

The authors attributed the outbreak to several factors. First, the index case had a severe case of pulmonary TB in which he produced copious amounts of sputum. Second, sixty percent of the emergency room air was recirculated without filtration adequate to remove TB bacilli, allowing for the recirculation of contaminated air. Finally, employees in the emergency room were provided surgical masks that were ineffective for protecting against transmission of airborne TB droplet nuclei. This study illustrates that the lack of effective measures for controlling TB transmission can result in the infection and development of active disease in a relatively high number of employees even after exposure to only one case of active TB.

Similarly, the lack of effective controls while performing high-hazard, cough-inducing procedures on individuals with infectious TB has also been shown to result in an increased risk of TB transmission. A 1990 report by Malasky et al. (Ex. 7–41) investigated the potential for TB transmission from high-hazard procedures by examining tuberculin skin test conversion rates among pulmonary physicians in training. In this study, questionnaires were sent annually, for 3 years, to training programs located in the top 25 cities for TB in 1983. The purpose of the study was to compare the conversion rates of pulmonary disease fellows to the conversion rates of infectious disease fellows. It was presumed that both groups have contact with patients with TB but that pulmonary disease fellows are usually more involved with invasive procedures such as bronchoscopies. Information requested on the questionnaires included the type of fellowship (i.e., pulmonary or infectious disease fellow), prior tuberculin skin test status, tuberculin status by the Mantoux technique at the end of the 3 year fellowship program, history of BCG vaccination, age, sex and ethnicity. In addition, the pulmonary disease fellows were asked to give information on the number of bronchoscopies they performed and their use of masks during the procedure.

Fourteen programs submitted data that were usable. Only programs that had both pulmonary and infectious disease fellows in the same system were used for the study. From this information, it was observed that 7 of 62 (11%) of the pulmonary fellows at risk converted their tuberculin skin test from negative to positive during the two year training period. In contrast, only 1 of 42 (2.4%) of the infectious disease fellows converted. The expected conversion rate from previous surveys was 2.3%. In addition, the pulmonary disease fellows were grouped according to tuberculin skin status. Skin test status was evaluated for its relationship to the number of bronchoscopies performed and the pattern of mask usage. No correlations were found with these factors and tuberculin skin status at the end of the fellowship. The authors suggested that the lack of correlation between mask usage during bronchoscopies and skin test conversion implies that masks worn by physicians may be inadequate. While little information was presented to evaluate this suggestion, the study does suggest that high-hazard procedures such as bronchoscopies that induce coughing, performed under uncontrolled conditions, present a risk for TB transmission.

Pearson *et al.* (1992) conducted a case-control study to investigate the factors associated with the development of MDR–TB among patients at a New

York City hospital (Ex. 5–24). As a part of this study, tuberculin skin test conversion rates were compared among health care workers assigned to wards where patients with TB were frequently admitted (e.g., HIV unit, general medical ward, respiratory therapy) or rarely admitted (operating room, orthopedic ward, outpatient clinic, psychiatry ward). In addition, infection control procedures and ventilation systems were evaluated.

Of 79 health care workers who were previously negative, 12 (15%) had newly positive skin tests. Those health care workers who were assigned to wards where patients with TB were frequently admitted were more likely to have skin test conversions (i.e., 11 of 32) than health care workers assigned to wards where patients with TB were rarely admitted (i.e., 1 of 47).

Evaluations of the infection control procedures and ventilation systems revealed that patients who were receiving isolation precautions for suspected or confirmed TB were allowed to go to common areas if they wore a surgical mask. However, many of the patients did not keep their masks on when out of their rooms. In addition, neither the isolation rooms nor rooms used for cough-inducing procedures were under negative pressure, thus allowing contaminated air to exhaust to the adjacent corridors.

Edlin *et al.* (1992) (Ex. 5–9) investigated an outbreak of MDR–TB in a New York hospital among patients with acquired immunodeficiency syndrome (AIDS). This study compared the exposure period of AIDS patients diagnosed with MDR–TB to the exposure period of AIDS patients with drug-susceptible TB. The date of diagnosis was defined as the date the sputum sample was collected from which tuberculosis bacteria were grown in culture. Patients were assumed to be infectious two weeks before and two weeks after the date of diagnosis. The period of exposure was the period in which the patient may have been infected with TB. Because of the rapid progression from infection to disease, the exposure period was defined as 6 months preceding the date of diagnosis, excluding the last two weeks.

The patients with MDR–TB were found to be more likely to have been hospitalized during their exposure periods. Those who were hospitalized were more likely to have been on the same ward and on the same day as a patient with infectious TB and were more likely to have been near a room housing an infectious patient. Examination of the infectious patients' rooms revealed that only 1 of 16 rooms had negative pressure. Based on this evidence, the authors concluded that the observed cases of MDR-TB were a likely result of infections acquired in the hospital (i.e., primary TB) rather than as a result of the reactivation of infections acquired in the past. The authors attributed these nosocomial infections to the lack of adherence to recommended infection control procedures.

While the primary focus of this study was to investigate the transmission of TB among patients, the increased likelihood of nosocomial infections among patients in the hospital would seem equally likely to apply to health care workers working in the same environment. A survey of tuberculin skin test conversions revealed an 18% conversion rate for health care workers who previously had negative skin tests and were present during this outbreak of MDR-TB. Although no statistics were reported, the authors stated that the pattern of skin test conversions suggested an ongoing risk over time rather than a recent increase during the outbreak period.

Based on an earlier 1990 report from the CDC (Ex. 5–22), Beck-Sague *et al.* 1992 (Ex. 5–21) conducted a case-control study to investigate an outbreak of MDR–TB among the staff and patients in a HIV ward and clinic of a Miami hospital. As part of the overall study the authors compared the skin test conversion rates of health care workers in the HIV ward and clinic to the skin test conversion rates of health care workers in the thoracic surgery ward where TB patients were rarely seen. In addition, the authors also evaluated the relationship between the presence of patients with infectious MDR–TB and patients with infectious drug-susceptible TB on the HIV ward and the risk of skin test conversion among the HIV ward health care workers. Infection control procedures in the HIV ward and clinic were also examined.

All patients with suspected or confirmed TB were placed in isolation. However, some patients whose complaints were not primarily pulmonary and whose chest X-rays were not highly suggestive of TB were not initially suspected of TB and were not placed in isolation. Patients who were admitted to isolation rooms were allowed to leave TB isolation 7 days after the initiation of chemotherapy regardless of clinical or bacteriologic response. Thus, in some instances, patients with MDR–TB were allowed to leave isolation while they were still infectious, before drug resistance was recognized. In addition, patients in isolation rooms sometimes left the doors open, left their rooms, and/or removed their masks while outside their rooms. Patients with TB who were readmitted to the HIV ward and who were receiving anti-TB drugs were not admitted to isolation. In some cases, these patients were later found to have infectious MDR–TB.

An environmental assessment of the ventilation revealed that among 23 rooms tested with smoke tubes, 6 had positive pressure and many of the rooms under negative pressure varied from negative to positive depending on the fan setting and whether the bathroom door was open. Aerosolized pentamidine administration rooms were also found to have positive pressure relative to adjacent treatment areas. In addition, the sputum induction rooms were found to recirculate air back to the HIV clinic.

Skin test conversions were evaluated for all health care workers (i.e., nurses and clerical staff) who tested negative on the tuberculin skin test before the outbreak period, March 1988 through April 1990. Health care workers on the HIV ward and in the HIV clinic exhibited a significantly higher rate of skin test conversion than health care workers on the thoracic surgery ward (e.g., 13/39 vs. 0/15). Ten of the conversions occurred among the 28 health care workers in the HIV ward. Among these health care workers, the authors reported a significant correlation between the risk of infection in health care workers and the number of days that patients with infectious MDR–TB were hospitalized on the HIV ward. No correlation was observed between the risk of infection among health care workers on the HIV ward and the number of days that patients with infectious drug-susceptible TB were hospitalized on the ward.

Based on skin test conversions and the evaluation of infection control practices in the HIV ward and clinic, the authors concluded that the health care workers most likely were infected by patients on the HIV ward with MDR–TB. The factors most likely contributing to this increased risk of infection included: (1) The prolonged infectiousness and greater number of days that patients with infectious MDR–TB were hospitalized, (2) the delayed recognition of TB and failure to suspect infectious TB in patients receiving what proved to be ineffective anti-TB treatment, (3) the inadequate duration of, and lapses in, isolation precautions on the HIV ward, and (4) the lack of negative pressure ventilation in isolation and treatment rooms. While the evidence in this study primarily points to the transmission of MDR–TB

from patients to health care workers, many of the problems identified with infection control procedures and ventilation would also increase the risk of acquiring drug-susceptible TB.

In addition to MDR–TB outbreak investigations in Miami, in 1993 the CDC reported an outbreak in New York City in which health care workers became infected after being exposed to patients with MDR–TB (Ex. 6–18). In this investigation, for the period December 1990 through March 1992, 32 patients were identified with MDR–TB. Twenty-eight of these patients had documented exposure to an undiagnosed infectious MDR–TB patient while all of them were in the HIV ward of the hospital.

During November 1991, health care workers who were assigned to the HIV inpatient unit and who were also previously negative on the tuberculin skin test, were given an additional skin test. Of 21 health care workers tested, 12 (57%) had converted to positive status (7 nurses, 4 aides and 1 clerical worker). None of the health care workers had used respiratory protection.

An investigation of infection control practices revealed that of 32 patients with MDR–TB, 16 were not initially suspected of TB and in these cases isolation precautions either were not used or were instituted late during the patients' hospitalization. In addition, patients who were admitted to isolation frequently left their rooms and when in their room the doors were frequently left open. Moreover, all rooms were found to be under positive pressure relative to the hall. Thus, similar to the findings in Miami, the results of this study indicate that the inability to properly isolate individuals with MDR–TB and also the use of inadequate respiratory protection may increase the risk of infection among health care workers.

Undiagnosed cases may also present a significant source for occupational transmission of TB. A case study by Cantanzaro (Ex. 5–14) described an outbreak of TB infection among hospital staff at a San Diego hospital where the hospital staff were exposed to a single patient with undiagnosed TB. In this case, a 64 year old man suffering from generalized seizures was transferred from a local jail to the emergency room and later admitted to a four bed intermediate care unit. While in the intermediate care unit he was treated with anticonvulsants but continued to have seizures accompanied with vomiting. He was therefore placed in intensive care where he underwent a variety of procedures including bronchoscopies and endotracheal intubation. During his stay, he received frequent chest therapy and suctioning. Three sputum samples were taken from the patient for smears and cultures. All AFB smears were negative. However, two cultures were positive for tuberculosis.

Despite the presence of positive cultures the patient was not diagnosed with active TB. The problem was not recognized until a physician on staff later developed symptoms of malaise and slight cough and requested a tuberculin skin test and was found to be positive. Because the physician had been tuberculin negative 8 months earlier, a contact investigation was initiated. As a part of this investigation, all employees who previously had negative tuberculin tests and who also worked in the intermediate and intensive care units where the patient had been treated were given repeat skin tests. Of 45 employees who previously had negative tuberculin skin tests, 14 (31%) converted to positive status (6 physicians, 3 nurses, 2 respiratory therapists and 1 clerk). Ten of these conversions were among the 13 previously tuberculin negative staff members who were present at the time bronchoscopies were conducted (10/13=76.9%). Four of the conversions were among 32 susceptible staff members who were not present at the bronchoscopies (4/32=12.5%). The author thus concluded that being present during the bronchoscopy of the patient was a major risk factor in acquiring the TB infection. However, the evidence did not show a significant correlation between skin test conversion and the type of exposure, i.e., close (administered direct contact) versus casual (in the room) contact. Thus, people who were present in the room during the bronchoscopy had an equal risk of infection as those administering direct patient care, presumably, as the author suggests, because droplet nuclei can disperse rapidly throughout the air of a room.

Similarly, Kantor *et al.* (Ex. 5–18) reported an outbreak of TB infection among hospital staff exposed to a single undiagnosed case of TB. The index case in this investigation was a 50 year old man who was admitted for lung cancer and was receiving chemotherapy, steroids and radiation treatment. After a month of treatment, the patient complained of a cough and chest pain and was found to have emphysema requiring additional drug treatment and a chest tube. However, even after the emphysema resolved, the patient complained of weakness, loss of appetite and fever. A sputum culture and smear were conducted for mycobacteria and found to be negative. Lung X-rays were found to be irregular but were attributed to the lung cancer. Upon his death the autopsy revealed extensive necrosis in the lung but tuberculosis was not suspected. Thus, no cultures for mycobacteria were performed and no infection control procedures were initiated. It was only upon histological examination of tissue samples one month later that the presence of TB was confirmed. Five months later one of the staff performing the autopsy developed active TB. His only history of exposure was to the index case.

As a result, a contact investigation was initiated for hospital personnel who had shared air with the patient during his stay, including the autopsy staff. Of susceptible hospital staff (i.e., those not previously found to react positive to the tuberculin skin test), infection developed in 9 of 56 (16%) exposed employees (4 autopsy staff, 4 nursing staff and 1 radiology staff). Only 3 of 333 unexposed personnel were found to have converted to positive tuberculin status at the hospital during the same period of investigation, thus indicating a 17.8 fold increase in the infection rate for the exposed group.

Undiagnosed cases of TB at time of autopsy were also indicated as the likely cause for development of active TB among staff and students in an autopsy room in a Swedish hospital (Ex. 5–19). In this study, three medical students and one autopsy technician, who were present during the autopsy of a patient with previously undiagnosed pulmonary TB, developed active TB. Both the medical students and the autopsy technician had previously received the BCG vaccine but none had any other known contact with a tuberculosis subject. Thus, it was concluded that the tuberculosis infections were most likely to have been transmitted during the autopsy. The findings of this study further illustrate the risks that undiagnosed cases of active TB present to health care workers. The lack of recognition of an active case of TB often results in a failure to initiate appropriate infection control procedures and provide appropriate personal protective equipment. In addition, this study illustrates that, while TB is most often transmitted by individuals with infectious pulmonary TB who generate droplet nuclei when they cough or speak, the autopsy procedures on deceased individuals with pulmonary TB may also aerosolize bacteria in the lungs and generate droplet nuclei.

Exposure during autopsy procedures was also suspected as a possible route of TB transmission in an upstate New

York Medical Examiner's Office (Ex. 7–152). This Medical Examiner's Office conducted autopsies on deceased inmates from upstate New York prisons. In 1991, the same year that an outbreak of MDR–TB occurred among inmates from an upstate New York prison, the Medical Examiner's office conducted autopsies on 8 inmates with TB, six of whom had infectious MDR–TB at death and who were also HIV positive and had disseminated TB disease.

Skin tests were administered to employees who had worked for at least one month during 1991 at the Medical Examiner's Office. Among 15 employees who had originally tested negative on a baseline skin test, 2 were found to have converted. These two employees worked as morgue assistants and had recent documented exposure to persons with extensive disseminated MDR–TB. No potential exposure to TB outside the Medical Examiner's Office could be found.

The autopsy area of the office had a separate ventilation system. However, air was returned to a common air plenum, allowing the air to mix between the autopsy area and other areas of the office. In addition, the autopsy room was found to be at positive pressure relative to the adjacent hallway. Employees performing or assisting at autopsies on persons known to be infected with HIV were required to wear plastic gowns, latex gloves and surgical masks. Particulate respirators were not required until November of 1991, after the installation of germicidal UV lamps. However, this was after the last MDR–TB autopsy. This study suggests that the conversion of these two morgue assistants occurred as a result of exposure to aerosolized *M. tuberculosis* resulting from autopsy procedures, either as a result of participation in an autopsy in the autopsy area or from exposure to air contaminated with aerosolized *M. tuberculosis* that was exhausted into other areas of the Medical Examiner's Office.

In addition to autopsy procedures, other procedures, such as the irrigation of abscesses at sites of extrapulmonary TB, can result in the generation of droplet nuclei. An outbreak investigation in an Arkansas hospital (Ex. 5–17) reported the transmission of TB among hospital employees exposed to a patient with a tuberculous abscess of the hip and thigh. In this study, the source case was a 67 year old man who was admitted to the hospital with a fever of unknown origin and progressive hip pain. The patient did not present any signs of pulmonary TB; however, the examination of soft tissue swelling in the hip area revealed an abscess that required drainage and irrigation. Due to the suspicion of TB, specimens for AFB smear and culture were obtained and the patient was placed in isolation. While in isolation, drainage from the abscess continued and irrigation of the abscess cavity was initiated on an 8-hour schedule. After four days, acid fast bacilli were observed in the AFB smears and TB therapy was begun. The patient remained in isolation until his death except for three days that he spent in the Intensive Care Unit (ICU) due to high fever.

An investigation of skin test surveys among the hospital employees revealed 55 skin test conversions among 442 previously nonreactive employees and 5 conversions among 50 medical students. In addition, 5 of the employees who had conversions also had active TB, including one who developed a tuberculous finger lesion at the site of a needle-stick injury incurred during the incision and drainage of the patient's abscess. All the skin test converters, except for two, recalled exposure to the source case. Of the 442 susceptible employees, 108 worked at least one day on one of the floors where the patient stayed (i.e., the surgical ward, the medical floor of the patient's room and the ICU). Four (80%) of 5 surgical suite employees who had direct contact with the patient through their assistance with the incision and irrigation of the patient's abscess had skin test conversions. In addition, 28 (85%) of 33 employees on the general medical floor and 6 (30%) of 20 ICU employees had skin test conversions. All those employees converting recalled exposure to the patient, some of whom had no direct contact with the patient.

Environmental studies revealed that two of the areas in which the patient stayed during his hospitalization did not have negative pressure. The isolation room was under positive pressure relative to adjacent rooms and the corridor. In addition, the patient's cubicle in the ICU had neutral pressure relative to the rest of the ICU. Employees in these two areas had skin test conversions even in cases where there was no direct patient contact. The lack of negative pressure was thought to have significantly contributed to the dispersion of droplet nuclei generated from the irrigation of the tuberculous abscess. In the surgical ward, air was directly exhausted to the outside. However, all employees present in the surgical ward when the patient was being treated had direct contact with the patient. There was no indication that the surgical staff had taken any special infection control precautions or had worn any personal protective equipment.

Thus, similar to other outbreak investigations, the lack of appropriate ventilation and respiratory protection stand out as the key factors in the transmission of TB to employees who are exposed to individuals with infectious TB. Moreover, this particular case study demonstrates that certain forms of extrapulmonary TB in conjunction with aerosolizing procedures, e.g., the irrigation of a tuberculous abscess, have the potential for presenting significant airborne exposures to *M. tuberculosis*.

Other aerosolizing procedures have also shown evidence of presenting airborne exposures to *M. tuberculosis*. For example, tissue processing was associated with the skin conversion of two pathologists working at a community hospital in California (Ex. 6–27). In this case study, after autopsy, a 62 year old man who had died from bronchogenic carcinoma was discovered to have a caseating lung lesion. A stain revealed a heavy concentration of acid-fast bacilli, which were identified in culture as *M. tuberculosis*. As a result, a contact investigation was initiated.

This investigation found twenty employees who had contact with the patient, including two pathologists and a laboratory assistant. All were given a tuberculin skin test and found to be negative. However, after follow-up skin testing three months later, the two pathologists had converted. Other than contact with the source case, the two had no other obvious sources of infection. One of the pathologists had been present at the autopsy. Both pathologists were present when the frozen lung sections were prepared. During this process, the lung tissue was sprayed with a compressed gas coolant, which created a heavy aerosol. Masks were not routinely worn during this tissue processing. The investigators suspected that this aerosol promoted the transmission of TB and was the likely cause of the observed infections.

While much of the health effects literature has focused on outbreaks of TB or MDR–TB, a more recent study investigated the status of infection control programs among ''non-outbreak'' hospitals (Ex. 7–147). Investigators from the Society of Health care Epidemiology of America (SHEA) and the CDC surveyed members of SHEA to assess compliance in the respondents' hospitals with the 1990 CDC Guidelines for Preventing the Transmission of TB in Health Care Facilities for the years 1989 to 1992. The survey included questions on tuberculin skin testing programs (e.g., frequency of testing,

positivity at hire, and percent newly converted), AFB isolation capabilities (e.g., negative pressure, air changes per hour, HEPA filtration) and respiratory protection.

The survey showed that of the 210 hospitals represented by the SHEA members' survey results, 193 (98%) admitted TB patients from 1989 to 1992, 40% of which had one or more patients with MDR–TB. In addition, the proportion of hospitals caring for drug susceptible TB patients rose from 88% to 92% and the proportion of hospitals caring for MDR–TB patients rose from 5% to 30%. While the number of hospitals caring for TB patients increased, the majority of those hospitals cared for a small number of patients. In 1992, approximately 89% of the hospitals reported 0 to 25 patients per year, while approximately 5% reported greater than 100 patients per year.

Few hospitals reported routine tuberculin skin testing for each of the years surveyed. For example, while 109 (52%) of the responding hospitals reported tuberculin skin test results for at least one of the years from 1989 to 1992, only 63 (30%) reported results for each of these years. When examining the conversion rates over time from 1989 to 1992, the investigators limited their analysis to the 63 hospitals reporting skin test data for each of these 4 years. Among these hospitals the median percentage of employees newly converting to positive skin test status remained constant over the 4 year period at approximately 0.34% per year (i.e., 3/1000 per year). However, when including all hospitals in the analysis, from 1989 to 1992, the number of hospitals reporting conversion rates increased from 63 to 109 and the conversion rates increased from 0.26% (i.e., 2/1000) to 0.50% (i.e., 5/1000).

With regard to AFB isolation capabilities, 62% of 181 responding hospitals reported that they had isolation facilities consistent with the 1990 CDC TB Guidelines (i.e., single-patient room, negative pressure, air directly exhausted outside, and ≥6 air changes per hour). Sixty-eight percent of the reporting hospitals had isolation facilities meeting the first three of these recommendations. For respiratory protection, the majority of health care workers in the hospitals used surgical masks. However, there was an increase in the use of dust-mist or dust-mist-fume respirators. The use of dust-mist respirators increased from 1 to 13% from 1989 to 1992 and the use of dust-mist-fume respirators increased from 0 to 10% for the same period. The only use of high efficiency particulate air (HEPA) filter respirators was by bronchoscopists and respiratory therapists at 4 hospitals.

As a second phase of this investigation, the survey responses were analyzed to determine the efficacy of the TB infection control programs among the member hospitals participating in the survey (Ex. 7–148). In this analysis, the reported conversion rates were compared to reported infection control measures (i.e., AFB isolation capabilities and respiratory protection). For purposes of comparison, hospitals were categorized as having either less than or ≥6 TB patients, less than or ≥437 beds, and admitting or not admitting MDR–TB patients.

Conversion rates were higher among health care workers from hospitals with ≥437 beds than among health care workers from smaller hospitals (0.9% vs. 0.6%, $p \leq 0.05$). This difference was more pronounced among ''higher-risk'' health care workers (i.e., health care workers including bronchoscopists and respiratory therapists). ''Higher-risk'' health care workers from hospitals with 437 or more beds had a 1.9% conversion rate compared to a conversion rate of 0.2% for ''higher-risk'' health care workers from smaller hospitals. Similarly, health care workers from hospitals where 6 or more TB patients were admitted per year had higher conversion rates than health care workers from hospitals with fewer than 6 TB patients per year (e.g., 1.2% vs. 0.6%).

For hospitals with 6 or more TB patients, conversion rates also varied depending on the level of TB infection control practices that were in place in the hospital. For example, among hospitals with 6 or more TB patients and whose AFB isolation capabilities included at least single-room occupancy, negative pressure and directly exhausted air, the conversion rates among health care workers were lower than the conversion rates among health care workers at hospitals with 6 or more TB patients but which did not have similar isolation capabilities (0.62% vs. 1.83%, $p=0.03$). For respiratory protection, however, no differences in conversion rates were observed among health care workers wearing surgical masks (0.94%) and health care workers using submicron surgical masks, dust-mist respirators or dust-mist-fume respirators (0.98%). Very few survey respondents reported use of HEPA filter respirators. For example, only four hospitals reported use of any HEPA respirators, and these were not the predominant type of respiratory protection used (Ex. 7–147). Thus, it is not possible to evaluate the efficacy of these particulate respirators in reducing conversion rates from the reported survey data.

For hospitals with fewer than 6 TB patients or with fewer than 437 beds, no differences in conversion rates were reported among health care workers from hospitals that had implemented AFB isolation capabilities such as single-room occupancy, negative pressure, or directly exhausted air and those hospitals that had not. The investigators suggested that this finding may support contentions that the efficacy of TB infection control measures vary depending on characteristics of the hospital or community exposure. However, given the small sample size of the survey, as well as the reduced potential for exposure in hospitals with fewer than 6 TB patients per year, it would be difficult to detect any differences in conversion rates among health care workers from hospitals with or without certain levels of infection control. Where more opportunity does exist for exposure (e.g., hospitals with ≥6 TB patients), this analysis does show that the implementation of TB infection control procedures can reduce the transmission of TB among health care workers.

Hospitals—Summary

In summary, the evidence clearly shows that in hospital settings, employees are at risk of occupational exposure to TB. Various studies and TB outbreak investigations have shown that employees exposed to individuals with infectious TB have converted to positive tuberculin skin status and in some cases have developed active disease. In these reports, a primary factor in the transmission of TB has been a failure to promptly identify individuals with infectious TB so that appropriate infection control measures could be initiated to prevent employee exposure. In addition, another major factor identified as contributing to occupational exposures was the lack or ineffective implementation of appropriate exposure control methods (e.g., lack of negative pressure in isolation rooms, lack of appropriate respiratory protection for exposed employees, performance of high-hazard procedures under uncontrolled conditions). The lack of early identification and appropriate control measures resulted in the exposure and subsequent infection of various hospital employees. These employees included not only health care providers administering direct patient care to individuals with infectious TB, but also hospital staff providing support services

to the infectious individuals, hospital staff working in adjacent areas of the hospital using shared air, autopsy staff and laboratory staff working with infected culture and tissue samples.

Other Occupational Settings

While hospitals have been historically recognized as the primary type of work setting where TB presents an occupational hazard, there are other work settings where the transmission of TB presents a hazard to workers. There are a variety of occupational settings in which workers can reasonably be anticipated to encounter individuals with active TB as a part of their job duties. Several work settings have been identified by the CDC where exposure to TB presents an occupational hazard: correctional facilities, long-term care facilities for the elderly, homeless shelters, drug treatment centers, emergency medical services, home-health care, and hospices. Similar to the hospital setting, these work settings have a higher number of individuals with active TB than would be expected for the general population. Many of the clients of these work settings have many characteristics (e.g., high prevalence of TB infection, high prevalence of HIV infection, intravenous drug use) that place them at an increased risk of developing active TB. These types of work settings are also similar to hospitals in that workers at these sites may also provide medical services and perform similar types of high-hazard procedures that are typically done in a hospital setting.

In addition to employees who provide medical services in these other types of work settings, there are other types of workers (e.g., guards, admissions staff, legal counsel for prisoners) who may also be exposed to individuals with infectious TB. Similar to hospitals, these work settings have an over-representation of populations at high risk for developing active TB, e.g., individuals infected with HIV, intravenous drug users, elderly individuals, and individuals with poor nutritional status and who are medically underserved. In addition to having a higher percentage of individuals with TB infection and a higher percentage of individuals at an increased risk for developing active TB, many of these work settings also share environmental factors that facilitate the transmission of TB, such as overcrowding and inadequate ventilation, which increases the occupational hazard. The following discussion describes some of the studies available in the literature that have examined the occupational transmission of TB in other occupational settings such as those listed above. Not all the settings listed by the CDC as places where TB transmission may be likely to occur have been adequately studied and thus can not be included in this discussion. However, the discussion of the following sectors clearly demonstrates that the occupational transmission of TB is not limited to the hospital setting. Occupational settings where there is an increased likelihood of exposure to aerosolized *M. tuberculosis* present the same types of occupational hazards as have been documented in the hospital setting.

Correctional Facilities

Many correctional facilities have a higher incidence of TB cases than occur in the general population. For example, the CDC reported that the incidence of TB among inmates of correctional facilities was more than three times higher than that for nonincarcerated adults aged 15–64, based on a survey of TB cases in 1984 and 1985 by 29 state health departments (Ex. 3–33). In particular, among inmates in the New York correctional system, the TB incidence increased from an annual average of 15.4 per 100,000 during 1976 to 1978 to 105.5 per 100,000 in 1986 (Ex. 7–80) to 156.2/100,000 for 1990–1991 (Ex. 7–137). Similarly, in 1987, the incidence of TB among inmates in New Jersey was 109.9 per 100,000 (approximately 11 times higher than the general population in New Jersey) and in California the incidence of TB among inmates was 80.3 per 100,000 (approximately 6 times higher than that for the general population for California) (Ex. 3–33). In 1989, the CDC reported that since 1985, eleven known outbreaks of TB have been recognized in prisons (Ex. 3–33).

The increased incidence of TB in correctional facilities has been attributed to several factors (Ex. 7–25). One, correctional facilities have a higher incidence of individuals who are at greater risk for developing active TB. For example, the population in prisons and jails may be dominated by persons from poor and minority groups, many of whom may be intravenous drug users. These particular groups may also suffer from poor nutritional status and poor health care, factors that place them at increased risk of developing active disease. Two, special types of correctional facilities, such as holding facilities associated with the Immigration and Naturalization Services, may have inmates/detainees from countries with a high incidence of TB. For foreign-born persons arriving in the U.S., the case rate of TB in 1989 was estimated to be 124 per 100,000, compared to an overall TB case rate of 9.5 per 100,000 for the U.S. (Ex. 6–26). In 1995, TB cases reported among the foreign born accounted for 35.7% of the total reported cases, marking a 63.3% increase since 1986 (Ex. 6–34). Three, many correctional facilities have a high proportion of individuals who are infected with HIV. The CDC reported that in addition to the growing increase in AIDS among prisoners, the incidence of AIDS in prisons is markedly higher than that for the U.S. general population. In 1988, the incidence of AIDS cases in the U.S. population was 13.7 per 100,000 compared to an estimated aggregate incidence for state/federal correctional systems of 75 cases per 100,000 (Ex. 3–33). Individuals who are infected with HIV or who have AIDS are at an increased risk of developing active TB due to their decreased immune capacity. The likelihood of pulmonary TB in individuals with HIV infection is reflected in the CDC's Revised Classification System for HIV infection (Ex. 6–30). In this revised classification system, the AIDS surveillance case definition was expanded to include pulmonary TB. Moreover, X-rays of individuals infected with HIV who have TB often exhibit radiographic irregularities that make the diagnosis of active TB difficult (Exs. 7–76, 7–77, 7–78, and 7–79). HIV-infected individuals may have concurrent pulmonary infections that confound the radiographic diagnosis of pulmonary TB. In addition, it may be difficult to distinguish symptoms of TB from *Pneumocystis carinii* pneumonia or other opportunistic infections. This difficulty in TB diagnosis can result in true cases of active TB going undiagnosed in this population. Undiagnosed TB has been shown to be an important cause of death in some patients with HIV infection (Ex. 7–76). Fourth, environmental conditions in correctional facilities can aid in the transmission of TB. For example, many prisons are old, have inadequate ventilation systems, and are overcrowded. In addition, inmates are frequently transferred both within and between facilities, thus increasing the potential for the spread of TB infection among inmates and staff. This increased potential for mobility among inmates also enhances the likelihood that inmates undergoing therapy for active disease will either discontinue their treatment or inadequately follow their prescribed regime of treatment. The inadequacy of their treatment may give rise not only to relapses to an infectious state of active disease, but also potentially give rise to strains of MDR–

TB. These strains of TB have a higher incidence of fatal outcome and are generally characterized by prolonged periods of infectiousness during which the risk of infection to others is increased.

The high incidence of TB among the inmate population presents an occupational hazard to the staff in these types of facilities. Recent outbreak investigations by the CDC have documented the transmission of TB to exposed workers. In an investigation of a state correctional facility in New York for 1991 (Exs. 6–3 and 7–136), eleven persons with TB were identified (10 inmates and one correctional facility guard). Nine persons (8 inmates and the guard) had MDR–TB. All eight inmates were HIV positive. The guard was HIV negative; however, he was also immunocompromised as a result of treatment for laryngeal cancer. Seven of the inmates and the guard died from MDR–TB. The eighth inmate was still alive and receiving treatment for MDR–TB 2 years after being diagnosed as having the disease. DNA analysis identified the strains of tuberculosis bacteria from these individuals to be identical.

The investigation revealed that the source case was an inmate who had been transferred from another prison where he had been previously exposed to MDR–TB. He arrived at the prison with infectious TB but refused evaluation by the infirmary staff. This inmate was placed in the general prison population where he stayed for 6 months until he was admitted to the hospital where he later died. However, before his hospitalization, he exposed two inmates living in his cell block who later developed MDR–TB. These two inmates continued to work and live in the prison until shortly before their final hospitalization. The other inmates who subsequently developed MDR–TB had several potential routes of exposure: social contact in the prison yard, contact at work sites in the prison, and contact at the prison infirmary where they shared rooms with other inmates before diagnosis with TB.

The guard who developed MDR–TB had exposure to inmates while transporting them to and from the hospital. The primary exposure for this guard apparently occurred when he was detailed outside the inmates' room during their hospitalization for MDR–TB. The inmates were hospitalized in an isolation room with negative pressure. However, upon investigation it was discovered that the ventilation system for the room had not been working correctly and had allowed air to be exhausted to the hospital corridors and other patient rooms.

A contact investigation in the prison was conducted to identify other inmates who might have been exposed during this outbreak of MDR–TB. Of those inmates with previous negative tuberculin skin tests and without active disease (306), ninety-two (30%) had documented skin test conversions. There was no tuberculin skin test program for prison staff; therefore, conversions among prison employees could not be evaluated.

The primary factors identified as contributing to this outbreak were deficiencies in identifying TB among transferred inmates, laboratory delays, and lapses in isolating inmates with active TB within the facility. Inmates with symptoms of active disease were not sent for evaluation in some cases until they became so ill they could not care for themselves. Some of these inmates were placed in the infirmary with other inmates until their diagnosis with TB. On other occasions, drug susceptibility testing was not reported until after an inmate's death, which means that appropriate patient management was not initiated.

As a result of this outbreak, a retrospective epidemiological investigation was conducted to examine the potential extent and spread of MDR–TB throughout the New York State prison system during the years 1990–1991 (Ex. 7–137). This investigation revealed that 69 cases of TB were diagnosed in 1990 and another 102 were diagnosed in 1991, resulting in a combined incidence of 156.2 cases/100,000 inmate years for 1990 and 1991 combined. Of the cases, 39 were identified as being MDR–TB, 31 of which were shown to be epidemiologically linked. Thirty-three of the individuals with MDR–TB never received any treatment for MDR–TB, 3 were diagnosed at death, and 23 died before drug susceptibility results were known. These inmates were also discovered to be highly mobile. The 39 inmates lived in 23 different prisons while they were potentially infectious. Twenty transfers were documented for 12 inmates with potentially infectious MDR–TB (9 shortly before diagnosis, one after diagnosis with TB but before diagnosis with MDR–TB, and 2 after a diagnosis of MDR–TB).

Several factors were identified as contributing to the spread of MDR–TB throughout the New York prison system: delays in identifying and isolating inmates, frequent transfers without appropriate medical evaluation, lapses in treatment, and delays in diagnosis and susceptibility testing.

A similar investigation in a California state correctional institution identified three active cases of TB (two inmates and one employee) during September and October 1991 (Ex. 6–5). As a result, an investigation was commenced to determine whether transmission of TB was ongoing in the institution. Eighteen inmates with active TB were identified. TB in 10 of these inmates was recognized for the first time while they were in the institution during 1991, resulting in an annual incidence of TB of 184 per 100,000, a rate greater than 10 times that for the state (17.4 per 100,000). Two of the 10 inmates had negative tuberculin skin tests prior to their entry into the institution. Three of the cases were determined to have been infectious during 1991.

A review of skin test data revealed that for the 2944 inmates for whom skin test results were available, 324 tested positive for the first time while in the prison system. Of these, 106 were tuberculin negative before their entry into the prison system, 96 of which occurred in the previous two years.

The employee identified as having active TB had worked as a counselor on the prison's HIV ward, where he recalled exposure to one of the 3 infectious inmates. This employee could recall no known exposures outside the prison. Similarly, two other prison employees had documented skin test conversions while working at the prison. Neither recalled exposures outside the prison; one reported exposure to an inmate with possible TB.

No information was provided in this report as to whether any isolation precautions were implemented at this facility. However, the investigators concluded that their findings suggested the likelihood that transmission of TB had occurred in the prison. Their conclusion was based on the fact that a substantial number of skin test conversions were documented among the inmates and that at least two inmates with active TB became infected while at the prison.

The transmission of TB was also reported in another California prison among prison infirmary physicians and nurses and correctional officers (Ex. 6–6). In this investigation, an inmate with active MDR–TB spent 6 months during 1990–1991 in the infirmary. The infirmary had no isolation rooms and inmates' cells were found to be under positive pressure. Employees occasionally recalled wearing surgical masks when entering the rooms of TB patients.

An analysis of available skin testing data revealed that of the 21 infirmary health care providers, only 10 had been

tested twice during the period from 1987 to 1990. Of these 10, two were newly positive, one of whom had recently converted in 1991 and had spent 5 months in the preceding year providing health care to the source case in this investigation. Another health care provider and a correctional officer who worked in the infirmary also were identified as having newly converted while at the prison. There was no yearly skin test screening, and thus their conversions could have occurred at any time between 1987 and 1991. However, 13 other inmates were diagnosed with pulmonary TB during that same period. An additional correctional officer who did not work in the infirmary also was found to have newly converted. His reported exposure occurred at a community hospital where he was assigned to an inmate with infectious TB. The officer was not provided with any respiratory protection. The lack of isolation precautions and the lack of appropriate respiratory protection suggest transmission of TB from infectious inmates in the infirmary to the prison staff, either as a result of exposure to the source case or other inmates with pulmonary TB who were also treated in the prison infirmary. Because of the lack of contact tracing or routine annual screening of inmates or staff, the full extent of transmission from the source case or other TB cases could not be determined.

Thus, similar to the evidence for the hospital setting, the evidence on correctional facilities shows that the failure to promptly identify individuals with infectious TB and provide appropriate infection control measures can result in the exposure and subsequent infection of employees with TB. These employees include the correctional facility infirmary staff, guards on duty at the facility, and guards assigned to escort inmates during transport to other facilities (e.g., outside health care facilities and other correctional facilities).

Homeless Shelters

Tuberculosis has also been recognized as a health hazard among homeless persons. The growth of the homeless population in the United States since the 1980s and the subsequent increase in the number of shelters for the homeless, furthers heightens the concern about the potential for the increased incidence and transmission of TB among the homeless, especially in crowded living conditions such as homeless shelters.

A number of factors are present in homeless shelters which increase the potential for the transmission of TB among the shelter residents and among the shelter staff. A high prevalence of TB infection and disease is common among many homeless shelters. This is not surprising, since the residents of these facilities usually come from lower socio-economic groups and often have characteristics that place them at high risk. Screening of selected clinics and shelters for the homeless has shown that the prevalence of TB infection ranges from 18 to 51% and the prevalence of clinically active disease ranges from 1.6 to 6.8% (Ex. 6–15). The CDC estimates this to be 150 to 300 times the nationwide prevalence rate (Ex. 6–17).

In addition to having a high prevalence of individuals with TB infection in the shelters, many of the shelter residents possess characteristics that impair their immunity and thus place them at a greater risk of developing active disease. For example, homeless persons generally suffer from poor nutrition, poor overall health status and poor access to health care. Many also suffer from alcoholism, drug abuse and psychological stress. Moreover, a significant portion of homeless shelter residents are infected with the HIV. In 1988, the Partnership of the Homeless Inc. conducted a survey of 45 of the nation's largest cities and estimated that there were between 5,000 and 8,000 homeless persons with AIDS in New York City and approximately 20,000 nationwide (Ex. 7–55). Due to these factors, homeless shelter residents are at increased risk of developing active disease. Thus, there is the increased likelihood that these individuals will be infectious as a result of active disease and thereby present a source of exposure for other homeless persons and for shelter employees.

In addition to having factors which increase their risk of developing active TB disease, homeless persons also are a very transient population. Because they are transient, homeless persons are more likely to discontinue or to erratically adhere to the prescribed TB therapy. Inadequately adhering to TB therapy can result in relapses to an infectious state of the disease or the development of MDR–TB. Both outcomes result in periods of infectiousness, during which they present a source of exposure to other residents and staff. In addition, environmental factors at homeless shelters, such as crowded living conditions and poor ventilation, facilitate the transmission of TB.

Outbreaks of TB among homeless shelter residents have been reported. For example, during 1990, 17 individuals with active pulmonary TB were identified among residents of homeless shelters in three Ohio cities: Cincinnati, Columbus, and Toledo (Ex. 7–51). In Cincinnati, 11 individuals with active TB were identified in a shelter for homeless adults. The index case was a man who had resided at the shelter and later died from respiratory failure. He was not diagnosed with TB until his autopsy. Of these 11 individuals, of which the index case was one, 7 were determined to be infectious. There was no indication as to whether any infection control measures were in place in the shelter. DNA analysis of 10 individual *M. tuberculosis* isolates showed identical patterns. The similarity among these DNA patterns suggested that transmission of the TB occurred in the shelter.

While the primary focus of this investigation was on the active cases reported among the residents in this Cincinnati shelter, the risk of transmission identified in this shelter also would apply to the shelter staff. Possible transmission of TB infection from the infectious individuals to the shelter staff might have been identified through tuberculin skin test conversions. However, no tuberculin skin test information for the staff was reported in this investigation.

Tuberculin skin testing results were reported in the investigation of a Columbus, Ohio shelter. In this investigation, a resident of a Columbus homeless shelter was identified with infectious pulmonary TB at the local hospital in March of 1990. The patient also had resided in a shelter in Toledo. As a result, a city-wide TB screening was initiated from April to May 1990 among the residents and staff of the city's men's shelters. Tuberculin skin tests were conducted on 363 shelter residents and 123 shelter employees. Among 81 skin-tested residents of the shelter in which the index case had resided, 32 (40%) were positive compared to 47 (22%) of 210 skin-tested residents of other shelters in Columbus who had positive skin test reactions. Similarly, among 27 employees of the shelter where the index case resided, 7 (26%) had positive skin test reactions compared to 9 (11%) of 85 employees in other men's shelters. These skin test results suggest an increased risk of transmission of TB among residents and employees of the homeless shelter where the index case resided. However, due to the lack of baseline skin test information among these residents and employees it is not possible to determine when their conversion to positive status occurred and whether this index case was their source of exposure. These results, however, do indicate a high prevalence of TB infection among homeless residents

(e.g., 40% and 22%). Many of these individuals are likely to have an increased risk of developing active TB and, as a result, they may present a source of exposure to residents and staff.

The transmission of TB has also been observed among residents and staff of several Boston homeless shelters (Exs. 7–75 and 6–25). From February 1984 through March 1985, 26 cases of TB were confirmed among homeless residents of three large shelters in Boston. Nineteen of the 26 cases occurred in 1984, thus giving an incidence of approximately 317 per 100,000, 6 times the homeless case rate of 50 per 100,000 reported for 1983 and nearly 16 times the 1984 case rate of 19 per 100,000 for the rest of Boston (Ex. 6–25).

Of the 26 cases of TB reported, 15 had MDR–TB. Phage typing of isolates from 13 of the individuals with drug-resistant TB showed identical phage types, thus suggesting a common source of exposure. As a result of this outbreak, a screening program was implemented in November 1984 over a four-night period. Of 362 people who received skin tests, 187 returned for reading, 42 (22%) were found to be positive and 3 were recent converters. Screening also was reported for the shelter staff at the three homeless facilities. At the largest of the three shelters, 17 of 85 (20%) staff members had skin test conversions. In the other two shelters, 3 of 15 (20%) and 3 of 18 (16%) staff members had skin test conversions.

Whereas MDR–TB was primarily involved in the outbreak in Boston, an outbreak of drug-susceptible TB was reported in a homeless shelter in Seattle, Washington (Ex. 7–73). From December 1986 to January 1987, seven cases of TB from homeless residents were reported to the Seattle Public Health Department. The report of 7 individuals with active TB in one month prompted an investigation, including: (1) A mass screening to detect undiagnosed cases, (2) phage typing of isolates from shelter clients to detect epidemiologically linked cases, and (3) a case-control study to investigate possible risk factors for the acquisition of TB.

A review of the case registries revealed that 9 individuals with active TB had been reported from the homeless shelter for the preceding year and four cases in the year previous to that. As a result of the mass screening in late January 1987, an additional 6 individuals with active TB were detected. Phage typing of 15 isolates from the shelter-associated cases revealed that 6 individuals with active TB diagnosed around the time of the outbreak were of the same phage type, suggesting that there was a predominant chain of infection, i.e., a single source of infection. However, there also were other phage types, suggesting several sources of infection. Therefore, the investigators suggested that there was probably a mixture of primary and reactivated cases.

In addition to the similarity of phage types among TB cases, tuberculin skin testing results suggested the ongoing transmission of TB in the shelter. For example, 10 shelter clients who were previously tuberculin negative in May 1985 were re-tested in January 1987 and 3 (30%) had converted. In addition, 43 clients who were negative in January 1987 were re-tested in June 1987 or February 1988 and 10 (23%) had converted. Factors identified as contributing to the outbreak were the increased number of men with undiagnosed infectious pulmonary TB, the close proximity of beds in the shelter, and a closed ventilation system that provided extensive recirculation of unfiltered air.

As a result of the outbreak, a control plan was implemented. This plan included repetitive mass screening, repetitive skin testing, directly observed therapy, preventive therapy and modification of the ventilation system to incorporate UV light disinfection in the ventilation duct work. After the control plan was in place, five additional individuals with active TB were observed over a 2-year follow-up period.

While the primary focus in this study was on clients of the shelter rather than the shelter staff, the risk factors present in the shelter before implementation of the control plan would have also increased the likelihood for transmission of TB to shelter employees from infectious clients.

Thus, similar to correctional facilities, homeless shelters have a number of risk factors that facilitate and promote the transmission of TB (e.g., high incidence of infected residents with an increased likelihood of developing active disease, crowded living conditions and poor ventilation). Also, similar to correctional facilities, the evidence in homeless shelters shows that the failure to promptly identify homeless residents with infectious TB and the lack of appropriate TB control measures (e.g., lack of isolation precautions or prompt transfer to facilities with adequate isolation precautions) resulted in the transmission of TB to shelter employees.

Long-Term Care Facilities for the Elderly

Long-term care facilities for the elderly also represent a high-risk population for the transmission of TB. TB disease in persons over the age of 65 constitutes a large proportion of TB in the United States. Many of these individuals were infected in the past, before the introduction of anti-TB drugs and TB control programs when the prevalence of TB disease was much greater among the general population, and have harbored latent infection over their lifetimes. However, with advancing age, these individuals' immune function starts to decline, placing them at increased risk of developing active TB disease. In addition, they may have underlying disease or overall poor health status. Moreover, residents are often clustered together and group activities are often encouraged. TB case rates are higher for this age group than for any other. For example, the CDC reports that in 1987, the 6,150 cases of TB disease reported for persons ≥65 years of age accounted for 27% of the U.S. TB morbidity although this group only represented 12% of the U.S. population (Ex. 6–14).

Because of the higher prevalence of TB cases among this age group, employees of facilities that provide long-term care for the elderly are at increased risk for the transmission of TB. More elderly persons live in nursing homes than in any other type of residential institution. The CDC's National Center for Health Statistics reports that elderly persons represent 88% of the nation's approximately 1.7 million nursing home residents. As noted by the CDC, the concentration of such high-risk individuals in long-term care facilities creates a high-risk situation for the transmission of TB (Ex. 6–14).

In addition to having a higher prevalence of active TB, the recognition of TB in elderly individuals may be difficult or delayed because of the atypical radiographic appearance that TB may have in elderly persons (Exs. 7–59, 7–81, 7–82, and 7–83). In this situation, individuals with active TB may go undiagnosed, providing a source of exposure to residents and staff.

While the increased incidence of TB cases among the elderly in long-term care facilities may be a result of the activation of latent TB infections, the transmission of TB infection to residents and staff from infectious cases in the facilities has been observed and reported in the scientific literature.

For example, Stead *et al.* (1985) examined the reactivity to the tuberculin skin test among nursing home residents in Arkansas (Ex. 7–59). This study involved a cross-sectional survey in which tuberculin skin tests were given to all current nursing home

residents. In addition, all newly-admitted nursing home residents were skin tested. For the three year period evaluated, 25,637 residents of the 223 nursing homes in Arkansas were tested.

Of 12,196 residents who were tested within one month of entry, only 12 percent were tuberculin positive, including those for whom a booster effect was detected. However, among the 13,441 residents for whom the first test was delayed for more than a month, 20.8% were positive. In addition, the results of retesting 9,937 persons who were tuberculin negative showed an annual conversion rate of approximately 5% in nursing homes in which an infectious TB case had been recognized in the last three years. In nursing homes with no recognized cases, the authors reported an annual conversion rate of approximately 3.5%. The authors concluded that their data supported the contention that tuberculosis may be a rather common nosocomial infection in nursing homes and that new infections with tuberculosis is an important risk for nursing home residents and staff.

Brennen *et al.* (Ex. 5–12) described an outbreak of TB that occurred in a chronic care Veteran's Administration Medical Center in Pittsburgh. This investigation was initiated as a result of two skin test conversions identified through the employee testing program. One converter was a nurse working on ward 1B (a locked ward for neuropsychiatric patients) and the other was a physician working in an adjacent ward, 1U, who also had significant exposure to ward 1B. The source of infection in this investigation was traced to two patients who had resided on ward 1B and who had either a delayed or undiagnosed case of TB. The contact investigation revealed 8 additional conversions among patients, 4 in ward 1B and 4 in wards 2B and 4B (units on the floor above 1B).

Because the source cases were initially unidentified, no isolation precautions were taken. Smoke tracer studies revealed that air discharged from the window air conditioning unit of one of the source patients discharged directly into the courtyard. Air from this courtyard was the air intake source for window air conditioning units in the converters' room on ward 2B and thus was one of the possible sources of exposure.

In addition to the contact investigation on ward 1B and the adjacent units, hospital-wide skin testing results were evaluated. Of 395 employees tested, 110 (28%) were positive. The prevalence in the surrounding community was estimated to be 8.8%. Of those employees initially negative, 38 (12%) converted to positive status. Included among these were employees in nursing (18), medical (3), dental (1), maintenance/engineering (3), supply (1), dietary (9), and clerical (2) services.

Occupational transmission of TB was also reported in a nursing home in Oklahoma (Ex. 6–28). In August 1978, a 68 year old female residing in the east wing of the home was diagnosed with pulmonary TB. She was subsequently hospitalized. However, by that time she had already had frequent contact with other residents in the east wing. As a result, a contact investigation, in which all residents of the home were given skin tests, was initiated.

The investigation revealed that the reaction rate for residents in the east wing (34/48, 71%) was significantly higher than the reaction rates of residents living in the north and front wings (30/87, 34%). No baseline skin test information was presented for the residents to determine the level of conversion. However, it was noted that half of the nursing home residents were former residents of a state institution for the developmentally disabled. A 1970 tuberculin skin test survey of that institution had shown a low rate of positive reactions.

In addition to the nursing home residents, nursing home employees were also skin tested. Of the 91 employees tested, 61 (67%) were negative and 30 (33%) were positive. Similar to results observed among the residents, positive reaction rates were higher for employees who had ever worked in the east wing (50%) than for those who had never worked in the east wing (23%). Retesting of the employees 3 months later revealed 3 conversions. These results suggested that there may have been occupational transmission of TB in this facility.

Occupational transmission has also been observed in a retrospective study of residents and employees who lived or worked in an Arkansas nursing home between 1972 and 1981 (Ex. 7-83). In this retrospective study, investigators reviewed the skin testing and medical chart data collected over a 10-year period at an Arkansas nursing home. Among the nursing home residents who were admitted between 1972 and 1982, 32 of 226 residents (17%) who were initially tuberculin negative upon admittance became infected while in the home, based on conversion to positive after at least two previous negative tests. Twenty-four (63%) of these conversions were infected in 1975, following exposure to one infectious resident. This resident, who had negative skin tests on three previous occasions during his stay in the home, was not diagnosed with TB until after he was hospitalized because of fever, loss of weight and productive cough. The remaining 37% converted in the absence of a known infectious case. Thus, the authors suggested that nosocomial infections are likely to result from persons unsuspected of having TB.

Skin testing was also reviewed for employees of the nursing home. Questionnaires were completed by 108 full-time employees. Eleven of 68 employees with follow-up skin tests converted to positive skin status during the study period. Ten of the 11 (91%) converters reported that they had been in the nursing home in 1975, the same year in which many of the residents were also found to have converted from a single infectious case. In addition, employees working at least 10 years in the home had a higher percentage of conversions (9 of 22, 40%) than employees working less than 10 years (2 of 46, 4.4%). Based on the results of this study, the authors concluded that, in addition to occurrence of TB cases from the reactivation of latent infections among the elderly, TB can also be transmitted from one resident to another resident or staff. Consequently, TB must be considered as a potential nosocomial infection in nursing homes.

Thus, long-term care facilities for the elderly represent a high-risk situation for the transmission of TB. These types of facilities possess a number of characteristics that increase the likelihood that active disease may be present among the facility residents and may go undetected. Similar to other high-risk settings, the evidence shows that the primary factors in the transmission of TB among residents and staff have been the failure to promptly identify residents with infectious TB and initiate and adequately implement appropriate exposure control measures.

Drug Treatment Centers

Another occupational setting that has been identified as a high-risk environment for the transmission of TB is drug treatment centers. Similar to other high-risk sites, drug treatment centers have a higher prevalence of TB infection than the general population. For example, in 1989 the CDC funded 25 state and city health departments to support tuberculin testing and administration of preventive therapy in conjunction with HIV counseling and testing. In this project, 28,586 clients from 114 drug treatment centers were given tuberculin skin tests. Of those, 2,645 (9.7%) were positive (Ex. 6–8). When persons with previously

documented positive tests were included, 4167 (13.3%) were positive.

There is also evidence to suggest that drug dependence is a risk factor for TB disease. For example, Reichman et al. (Ex. 7–85) evaluated the prevalence of TB disease among different drug-dependent populations in New York: (1) An in-hospital population, (2) a population in a local drug treatment center, and (3) a city-wide population in methadone clinics. For the in-hospital population of 1,283 patients discharged with drug dependence, 48 (3.74%) had active disease, for a prevalence rate of 3,740 per 100,000. In comparison, the TB prevalence rate for the total inpatient population was 584 per 100,000 and for New York City as a whole was 86.7 per 100,000. Screening of clients at a local drug treatment center in Harlem revealed a TB prevalence of 3750 per 100,000 in the drug-dependent population. Similarly, in the New York methadone program, the city-wide TB prevalence was 1,372 per 100,000. The authors also reported that although estimates of TB infection rates for both drug-dependent and non-drug dependent people were similar, the prevalence of TB disease among the drug-dependent was higher, thus suggesting that drug dependency may be a risk factor for disease.

Clients of drug treatment centers not only have a high prevalence of TB infection, a majority of them are intravenous drug users. Of the estimated 645,000 clients discharged each year from drug treatment centers, approximately 265,000 are intravenous drug users who either have or are at risk for HIV infection. In the Northeastern U.S., HIV seroprevalence rates of up to 49% have been reported (Ex. 6–8). These individuals are at increased risk of developing active TB disease.

To determine the risk of active TB associated with HIV infection, Selwyn *et al.* (Ex. 5–6) prospectively studied 520 intravenous drug users enrolled in a methadone maintenance program. In this study, 217 HIV seropositive and 303 seronegative intravenous drug users, who had complete medical records documenting their history of TB and skin test status, were followed from June 1985 to January 1988. On admission to the methadone program, and at yearly intervals, all patients were given tuberculin skin tests.

Forty-nine (23%) of the seropositive patients and 62 (20%) of the seronegative patients had positive reactions to the skin test before entry into the study. Among the patients who initially had negative skin tests, 15 of 131 (11%) seropositive patients and 62 of 303 (13%) seronegative patients converted to positive tuberculin status. While the prevalence and incidence rates of TB infection were similar for the two groups of patients, seropositive patients showed a higher incidence of developing active disease. Active TB developed in 8 of the seropositive subjects with TB infection (4%), whereas none of the seronegative patients with TB infection developed active TB during the study period.

Among individuals who are infected with HIV or who have AIDS, TB disease may be difficult to diagnosis because of the atypical radiographic appearance that TB may present in these individuals. In these individuals, TB may go undiagnosed and present an unsuspected source of exposure. Clients of drug treatment centers also may be more likely to discontinue or inadequately adhere to TB therapy regimens in instances where they develop active disease. As in other instances, this increases the likelihood of relapse to active disease or possibly the development of MDR–TB, both of which result in additional or even prolonged periods of infectiousness during which other clients or staff can be exposed.

There is evidence showing the transmission of TB in drug treatment facilities among both the clients and the staff. In a CDC case study (Ex. 5–6), a Michigan man who was living in a residential substance abuse treatment facility and was undergoing therapy for a previously diagnosed case of TB disease, was discovered by the local health department to have MDR–TB. As a result, a contact investigation was initiated at the drug treatment facility in which he resided.

Of the 160 clients and staff who were identified as potential contacts, 146 were tested and given tuberculin skin tests in November. No health screening program had been in place at the facility. The following March repeat skin tests were given. Of the 70 persons who were initially tuberculin negative and were still present in the facility, 15 (21%) had converted to positive status (14 clients and 1 staff member). The investigators noted that the number of converters may have been underestimated for two reasons. Many of the clients were at risk for HIV infection and thus may have been anergic and not responded to the tuberculin skin tests. In addition, nearly half of the clients who were initially negative were not available for repeat skin testing.

Several factors may have contributed to the observed conversions in this facility. For example, no health screening program was in place. Therefore, individuals with TB would go unidentified. In addition, the clients were housed in a building with crowded dormitories for sleeping. The only ventilation in this building was provided by opening windows and doors. Thus, environmental conditions were ideal for the transmission of TB.

Consequently, the high-risk characteristics of clients who frequent these centers (e.g., high prevalence of infection and factors increasing the likelihood of developing active disease) and environmental characteristics of the center (e.g., crowding and poor ventilation), lead to drug treatment centers being considered a high-risk setting for the transmission of TB. The available evidence shows that the failure to promptly identify clients with infectious TB and to initiate and properly implement exposure control methods (e.g., proper ventilation) resulted in the infection of clients and staff at these facilities.

Conclusion

The available evidence clearly demonstrates that the transmission of TB represents an occupational hazard in work settings where employees can reasonably be anticipated to have contact with individuals with infectious TB or air that may reasonably be anticipated to contain aerosolized *M. tuberculosis* as a part of their job duties. Epidemiological studies, case reports, and outbreak investigations have shown that in various work settings where there has been an increased likelihood of encountering individuals with active TB or where high-hazard procedures are performed, employees have become infected with TB and in some cases developed active disease. While some infections were a result of more direct and more prolonged exposures, other infections resulted from non-direct and brief or intermittent exposures. Because of the variability in the infectiousness of individuals with active TB, one exposure may be sufficient to initiate infection.

Several factors, common to many of these work settings, were identified as contributing to the transmission of TB: (1) Failure or delayed recognition of individuals with active TB within the facility, and (2) failure to initiate or adequately implement appropriate infection control measures (e.g., performance of high-hazard procedures under uncontrolled conditions, lack of negative pressure ventilation, recirculation of unfiltered air, and lack of appropriate respiratory protection). Thus, in work settings where employees can reasonably be anticipated to have contact with individuals with infectious

TB or air that may contain aerosolized *M. tuberculosis* and where appropriate infection control programs are not in place, employees are at increased risk of becoming infected with TB.

Infection with TB is a material impairment of the worker's health. Even though not all infections progress to active disease, infection marks a significant change in an individual's health status. Once infected, the individual is infected for his or her entire life and carries a lifetime risk of developing active disease, a risk they would not have had they not been infected. In addition, many individuals with infection undergo preventive therapy to stop the progression of infection to active disease. Preventive therapy consists of very toxic drugs that can cause serious adverse health effects and, in some cases, may be fatal.

Although treatable, active disease is also a serious adverse health effect. Some TB cases, even though cured, may result in long-term damage to the organ that is infected. Individuals with active disease may need to be hospitalized while they are infectious and they must take toxic drugs to stop the progressive destruction of the infected tissue. These drugs, as noted above, are toxic and may have serious side effects. Moreover, even with advancements in treating TB, individuals still die from TB disease. This problem is compounded by the emergence of multidrug-resistant strains of TB. In these cases, due to the inability to find adequate drug regimens which can treat the disease, individuals remain infectious longer, allowing the disease to progress further and cause more progressive destruction of the infected tissue. This increases the likelihood of long-term damage and death.

V. Preliminary Risk Assessment for Occupational Exposure to Tuberculosis

Introduction

The United States Supreme Court, in the ''benzene'' decision (*Industrial Union Department, AFL–CIO* v. *American Petroleum Institute,* 448 U.S. 607 (1980)), has stated the OSH Act requires that, prior to the issuance of a new standard, a determination must be made, based on substantial evidence in the record considered as a whole, that there is a significant health risk under existing conditions and that issuance of a new standard will significantly reduce or eliminate that risk. The Court stated that

> ''before he can promulgate any permanent health or safety standard, the Secretary is required to make a threshold finding that a place of employment is unsafe in the sense that significant risks are present and can be eliminated or lessened by a change in practices'' (448 U.S. 642).

The Court in the Cotton Dust case (*American Textile Manufacturers Institute* v. *Donovan,* 452 U.S. 490 (1981)), rejected the use of cost-benefit analysis in setting OSHA health standards. However, the Court reaffirmed its previous position in the ''benzene'' case that a risk assessment is not only appropriate, but also required to identify significant health risk in workers and to determine if a proposed standard will achieve a reduction in that risk. Although the Court did not require OSHA to perform a quantitative risk assessment in every case, the Court implied, and OSHA as a matter of policy agrees, that assessments should be put into quantitative terms to the extent possible. The following paragraphs present an overall description of OSHA's preliminary quantitative risk assessment for occupational exposure to tuberculosis (TB).

An earlier version of this risk assessment was reviewed by a group of four experts in the fields of TB epidemiology and mathematical modeling. The reviewers were George Comstock, MD, MPH, DPH, Alumni Centennial Professor of Epidemiology, The Johns Hopkins University; Neil Graham MBBS, MD, MPH, Associate Professor of Epidemiology, The Johns Hopkins University; Bahjat Qaqish, MD, PhD, Assistant Professor of Biostatistics, University of North Carolina; and Patricia M. Simone, MD, Chief, Program Services Branch, Division of Tuberculosis Elimination, CDC. The reader is referred to the peer review report in the docket for additional details (Ex. 7–911). The revised version of OSHA's risk assessment, as published in this proposed rule, includes OSHA's response to the reviewers' comments as well as updated risk estimates based on recent purified protein derivative (PPD) skin testing data made available to the Agency since the peer review was performed and is generally supported by the reviewers or is consistent with reviewers' comments. (Note: PPD skin test and tuberculin skin test (TST) are synonymous terms.)

The CDC estimates that, once infected with *M. tuberculosis*, an untreated individual has a 10% lifetime probability of developing active TB and that approximately half of those cases will develop within the first or second year after infection occurs. Individuals with active TB represent a pool from which the disease may spread. Based on data from the CDC, OSHA estimates that every index case (i.e., a person with infectious TB) results in at least 2 other infections (Ex. 7–269). For some percentage of active cases, a more severe clinical course can develop which can be attributed to various factors such as the presence of MDR–TB, an allergic response to treatment, or the synergistic effects of other health conditions an individual might have. Further, OSHA estimates that for 7.78% of active TB cases, TB is expected to be the cause of death. Section 6(b)(5) of the OSH Act states that,

> The Secretary, in promulgating standards dealing with toxic materials or harmful physical agents under this subsection, shall set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life.

For this rulemaking, OSHA defines TB infection as a ''material impairment of health'', for several reasons. First, once infected with TB, an individual has a 10% lifetime likelihood of developing active disease and approximately 1% likelihood of developing more serious complications leading to death. Second, allergic reaction and hepatic toxicity due to chemoprophylaxis with isoniazid, which is one of the drugs used in the recommended course of preventive treatment, pose a serious threat to a large number of workers. Third, defining infection with *M. tuberculosis* as material impairment of health is consistent with OSHA's position in the Bloodborne Pathogens standard and is supported by CDC and several stakeholders who participated in the pre-proposal meetings, as well as Dr. Neil Graham, one of the peer reviewers of this risk assessment. In his comments to OSHA, Dr. Graham stated,

> The focus of OSHA on risk of TB infection rather than TB disease is appropriate. TB infection is a potentially adverse event, particularly if exposure is from a MDR–TB patient, or if the health-care or institutional worker is HIV seropositive. In addition, a skin test conversion will in most cases mandate use of chemoprophylaxis for >6 months which is at least inconvenient and at worst may involve adverse drug reactions. (Ex. 7–271)

The approach taken in this risk assessment is similar to the approach OSHA took in its risk assessment for the Bloodborne Pathogens standard. As with bloodborne pathogens, the health response (i.e., infection) associated with exposure to the pathogenic agent does not depend on a cumulative level of exposure; instead, it is a function of intensity and frequency of each

exposure incident. However, unlike hepatitis B, where the likelihood of infection once an exposure incident occurs is known with some degree of certainty, the likelihood of becoming infected with TB after an exposure incident is not as well characterized. With TB, the likelihood of infection depends on the potency of an exposure incident and the susceptibility of the exposed individual (which is a function of the person's natural resistance to TB and his or her health status). Further, the potency of a given exposure incident is highly dependent on several factors, such as the concentration of droplet nuclei in the air, the duration of exposure, and the virulence of the pathogen (e.g., pulmonary and laryngeal TB are considered more infectious than other types).

The Agency has sufficient data to quantify the risk associated with occupational exposure to TB among health care workers in hospitals on a state-by-state basis. In addition to hospital employee data, OSHA has obtained data on selected health care employee groups from the TB Control Office of the Washington State Health Department. These groups include workers employed in long-term health care, home health care, and home care. Small entities are encouraged to comment and submit any data or studies on TB infection rates relevant to their business.

Because it is exposure to aerosolized *M. tuberculosis* that places workers at risk of infection, and not some factor unique to the health care profession, the Agency concluded that the experience of these groups of health care workers is representative of that of the other ''high-risk'' workers covered by this proposal. This means that the risk estimates calculated for these groups of workers are appropriate to use as the basis for describing the potential range of risks for workers in other work settings where workers can be expected to come into close and frequent contact with individuals with infectious TB (or with other sources of aerosolized *M. tuberculosis*) as an integral part of their job duties. As discussed in section IV (Health Effects), epidemiological studies, case reports, and outbreak investigations have shown that workers in various work settings, including but not limited to hospitals, have become infected with tuberculosis as a result of occupational exposure to aerosolized *M. tuberculosis* when appropriate infection control programs for tuberculosis were not in place.

In this preliminary risk assessment, OSHA presents risk estimates for TB infections, cases of active disease, and TB-related deaths (i.e., where TB is considered the cause or a major contributing cause of death) for workers with occupational exposure to tuberculosis.

A number of epidemiological studies demonstrate an increased risk of TB infection among health care workers in hospitals and other work settings. A brief review of a selection of these studies is presented below, followed by OSHA's estimates of excess risk due to occupational exposure. Finally, OSHA presents a qualitative assessment of the risk of TB infection caused by occupational exposure to tuberculosis in correctional facilities, homeless shelters, drug treatment centers, medical laboratories, and other high-risk work groups.

Review of the Epidemiology of TB Infection in Exposed Workers

There are several studies in the published scientific literature demonstrating the occupational transmission of infectious TB. Reports of TB outbreaks and epidemiologic surveillance studies have shown that health care and certain other workers are, as a result of their job duties, at significantly higher risk of becoming infected than the average person.

OSHA conducted a thorough search of the published literature and reviewed all studies addressing occupational exposure to tuberculosis and TB infection in hospitals and other work settings. All published studies show positive results (i.e., workers exposed to infectious individuals have a high likelihood of becoming infected with TB). Because there are so many studies, OSHA selected a representative subset of the more recent studies conducted in the U.S. to include in this section. These studies were chosen because they show occupational exposure in various work settings, under various working conditions, and under various scientific study designs.

OSHA's summary of the studies is presented in Table V–1(a) and Table V–1(b). These studies represent a wide range of occupational settings in hospitals, ranging from TB and HIV wards in high prevalence areas, such as New York City and Miami, to hospitals with no known TB patients located in low prevalence areas such as the state of Washington. The studies include prospective studies of entire hospitals or groups of hospitals, retrospective surveys of well-controlled clinical environments, such as an HIV ward in a hospital, and case studies of single-source infection (i.e., outbreak investigations).

TABLE V–1(A).—OUTBREAK INVESTIGATIONS OF TB INFECTION

Authors/year	Setting/source	Risk of TB in health care workers	Contributing factors
Catanzaro (1982)	Hospital intensive care unit/San Diego/1 index case—7-day hospital stay.	14/45 (31%) PPD conversions, 10/13 (77%) PPD conversions among health care workers present at bronchoscopy.	Poor ventilation. No report on respirator use.
Kantor et al. (1988)	VA hospital in Chicago autopsy room/1 index case undiagnosed until histology exam of autopsy tissue.	9/56 (16%) PPD conversions among exposed workers vs. 3/333 (1%) conversions among unexposed (RR=17.8) 3 workers developed active TB.	No mechanical ventilation on medical ward (autopsy room): no isolation. Autopsy room had 11 air changes/hour and no air recirculation.
Beck-Sague (1992)	Jackson Memorial Hospital in Miami MDR–TB in HIV/patients on HIV ward and clinic during 1989–91.	13/39 (33%) PPD conversions on HIV ward and clinic.	Some rooms had positive pressure. Inadequate triage of patients with suspected TB. Delay in use of isolation. Early discharge from isolation.

TABLE V–1(B).—SURVEILLANCE STUDIES OF TB INFECTION IN EXPOSED HEALTH CARE WORKERS

Authors/year	Setting/source	Study period	Population	Risk of TB in health care workers	Comments
Price et al. (1987)	19 Eastern North Carolina hospitals.	1980–84	All Hospital workers	1.80% annual PPD conversion rate.	
	29 Central North Carolina hospitals.	.....	.....	0.70% annual PPD conversion rate.	
	8 Western North Carolina hospitals.	.....	.....	0.61% annual PPD conversion rate.	
Aitken et al. (1987)	64 hospitals in Washington State.	1982–84	All Hospital workers	0.1% PPD conversion rate/in 3 years.	Strict adherence to CDC guidelines.
Malasky et al. (1990)	14 urban hospitals in U.S	(1)	Physicians in training in pulmonary medicine and infectious disease.	11% PPD conversion/3 years among pulmonary fellows, 2.4% PPD conversions/3 years among infectious disease fellows.	
Dooley et al. (1992) ..	Hospital in Puerto Rico TB in HIV-infected patients.	1989–90	Hospital workers (n=908)	Prevalence study: 54/109 (50%) nurses exposed to TB patients had positive PPDs 35/188 (19%) clerical workers with no exposure to TB had positive PPDs (p<0.001).	Isolation rooms did not have negative pressure. Recirculated air was not filtered.
NIOSH	Jackson Memorial Hospital, Miami.	1989–92	Hospital workers in selected wards (n=607).	60% annual PPD conversion among 263 exposed workers, 0.6% annual PPD conversion among 344 unexposed workers.	Incomplete isolation facilities. Improper application of isolation procedures.
Cocchiarella et al. (1996).	Cook County Hospital, Chicago.	1991	Graduating physicians with at least 1 year of clinical work at CCH (n=128).	18.8% 3-year PPD conversion rate for house staff in internal medicine vs. 2.2% PPD conversion rate for house staff in other specialties.	Residents were offered limited respiratory protection during exposures. No protocol available for early identification of suspect TB cases. PPD testing program incomplete. Inadequate isolation facilities.

[1] Mid 1980's (3 years).

Outbreak investigations describe occupational exposure to tuberculosis from single index patients or a well-defined group of patients. Such investigations are more likely to demonstrate an upper limit of occupational risk in different settings, usually under conditions of suboptimal environmental and infection controls. Although outbreak investigations demonstrate the existence of occupational risk under certain conditions and the importance of the early identification of suspect TB patients quite well, these studies do not provide information conducive to risk assessment estimations. Limitations of outbreak investigations include the frequent absence of baseline PPD test results, the difficulty of extrapolating the results to non-outbreak conditions of TB exposure, and, often, small sample sizes. Table V–1(a) lists some of the published outbreak investigations and shows the risks posed to health care workers by such outbreaks, as well as the failures in control programs contributing to these episodes.

Prospective and/or retrospective surveillance studies are used to estimate conversion rates from negative to positive in PPD skin testing programs. These conversion rates can be used to estimate the excess incidence of TB infection. Surveillance studies among health care workers lend themselves to a more systematic evaluation of the risk of TB infection than outbreak investigations, for several reasons. First, these studies better reflect the risk of TB experienced by workers under routine conditions of exposure. Second, these studies are usually based on a larger group of workers and therefore yield more precise and accurate estimates of the actual risk of infection. However, the extent to which results from surveillance studies can be generalized depends on a careful evaluation of the study population. Some studies report skin test conversion rates for all workers in the hospital(s) under study. Such studies often include large groups of employees with little or no exposure to TB. Results from such studies may reflect an overall estimate of risk in that environment, but may underestimate the occupational risk of those with frequent exposure.

Other surveillance studies report PPD conversion rates of more narrowly-defined groups of workers, usually those working in ''high-risk'' areas within a hospital such as the HIV or TB wards. Some of these studies have internal control groups (i.e., they compare PPD conversion rates between a group of workers with extensive exposure to TB and a group of workers with minimal or no exposure to TB), thus making it possible to more precisely quantify the magnitude of excess risk due to occupational exposure. However, these studies are also limited in their usefulness for risk assessment purposes. They usually have small sample sizes, making it more difficult to observe statistically significant differences. More

importantly, internal control groups may overestimate background risk, and thus underestimate excess occupational risk, unless painstaking efforts are made to eliminate from the control group those individuals with the potential for occupational exposure, a difficult task in some hospital environments. Table V–1(b) contains a selected list of published surveillance studies.

In reviewing Table V–1(a) and Table V–1(b), the reader should bear in mind that these tables are not intended to present an exhaustive list of epidemiologic studies with TB conversion rates in occupational settings. Instead, these tables present brief summaries of some of the epidemiologic evidence of occupational TB transmission found in the published literature; they are intended to convey the seriousness of the risk posed to health care workers and to illustrate how failures in control programs contribute to this risk. Upon reviewing these studies, a consistent pattern emerges: these work settings are associated with a high likelihood for occupational exposure to tuberculosis, and high rates of TB infection are being observed among health care workers.

Quantitative Assessment of Risk

Data availability usually dictates the direction and analytical approach OSHA's risk assessment can take. For this rulemaking, three health endpoints will be used: (1) TB infection, which is ''material impairment of health'' for this proposed standard; (2) Active disease following infection; and, (3) Risk of death from active TB.

In order to account for regional variability in TB prevalence and therefore to account for expected variability in the risk of TB infection in different areas, the Agency chose to develop occupational risk estimates on a state-by-state basis. This approach was criticized by Dr. Neil Graham as being too broad and ''* * * insufficient in light of the tremendous variability * * * that can occur within a state.'' (Ex. 7–911). The Agency recognizes that risk estimates on a county-by-county basis would be preferable; however, the unavailability of comprehensive county data has prevented the Agency from conducting such analysis.

The annual excess risk of TB infection due to occupational exposure is defined as a multiplicative function of the background rate of infection and is expressed as:

$p = ERR_o * R_b$

where:

p is the annual excess risk due to occupational exposure,

R_b is the background rate of TB infection, and

ERR_o is a multiplicative factor denoting the excess relative risk due to occupational exposure (ERR_o).

Estimates of ERR_o are derived from surveillance studies of workers with occupational exposure to TB. ERR_o is defined as the relative difference between the overall exposed worker risk and the background (population) risk and is calculated as the difference between overall worker and background risk divided by the background risk.

The annual excess risk due to occupational exposure is defined as a function of the background risk because of data limitations. If data on overall worker risk were available for each state, then the excess risk due to occupational exposure would simply be the difference between overall worker risk and background risk. Instead, the annual excess risk due to occupational exposure (i.e., p) is estimated using a multiplicative model because data on overall worker risk (i.e., R_w) were available only for the states of Washington, and North Carolina and for Jackson Memorial Hospital located in Miami, Florida. Therefore, the annual excess risk due to occupational exposure in state i (p_i) is expressed as:

$$p_i = \frac{\left(R_{wj} - R_{bj}\right)}{R_{bj}} * R_{bi}$$

where:

R_{wj} is the overall worker risk estimated from surveillance studies (study j),

R_{bj} is the study control group risk (i.e., study background risk), and

R_{bi} is the background rate for state i.

When i=j (i.e., Washington State or North Carolina), the excess risk due to occupational exposure, is expressed as the straight difference between overall worker risk and background risk.

OSHA calculated estimates of ERR_o based on three occupational studies: the Washington State study, the North Carolina study, and the Jackson Memorial Hospital study (Exs. 7–263, 7–7, 7–108). These estimates were expressed as percent change above each study's background. The derivation of these estimates is described in section 2.

In order to estimate an overall range of occupational risk of TB infection, taking into account regional differences in TB prevalence in the U.S., OSHA: (1) Estimated background TB infection rates by state (R_{bi}), and (2) applied estimates of ERR_o, derived from the occupational studies, to the state background rates to calculate estimates of excess risk due to occupational exposure by state.

OSHA used a multiplicative function of each state's background infection rate to estimate excess risk of TB infection because the probability of occupational infection can be viewed as a function of the number of contacts and frequency of contacts with infectious individuals. Thus, estimates of expected relative increase in risk above background due to occupational exposure are calculated for the three available studies and these relative increases (i.e. ERR_o) are multiplied by background rates for each state to derive estimates of excess occupational risk by state. These state estimates are then used to derive a national estimate of occupational risk.

The CDC compiles and publishes national statistics on the incidence of active TB in the U.S. by state based on reported cases. OSHA relied on these data to estimate TB infection background rates through the use of a mathematical model because information on TB infection is not being collected nationwide by CDC. A more detailed discussion on the methodology and derivation of background risk estimates by state is found in section 3, and discussion on the estimation of occupational risk estimates by state is found in section 4 of this risk assessment.

Because section 6(b)(5) of the OSH Act requires OSHA to assess lifetime risks, OSHA has converted the annual excess risk due to occupational exposure into an excess lifetime risk based on a 45-year working lifetime. The formula used to calculate lifetime occupational risk estimates of the probability of at least one occurrence of TB infection due to occupational exposure in 45 years is expressed as $\{1-(1-p)^{45}\}$, where p is the annual excess risk due to occupational exposure. Two assumptions are critical in defining lifetime risk: (1) the exposure period is 45 years, and (2) the annual excess risk remains constant. The implication of the second assumption is that the worker's exposure profile and working conditions, which may affect the level and intensity of exposure, and the virulence of the pathogen, remain unchanged throughout a working lifetime. The merit of this assumption was questioned by Dr. Graham, because, as he states ''* * * patient contact may vary greatly throughout a career for many HCWs [health care workers].'' and '' * * * physicians (and nurses) often do not have extensive patient contact until [their] mid-twenties, while other workers increasingly retire early.'' Dr. Graham recommends that OSHA's risk assessment be adjusted to account for variable exposure levels and variable working lifetimes. Although accounting

for variable exposure levels could result in more precise risk estimates, the unavailability of comprehensive information on lifetime TB exposure scenarios by occupational group prevented the Agency from developing a more complex risk model.

OSHA has customarily assumed a 45 year working lifetime in setting health standards. The Agency believes that this assumption is reasonable and consistent with the Act. The Act requires the Secretary to set a standard for toxic substances that would assure ''no employee * * * suffer material impairment of health or functional capacity *even if such employee has regular exposures to the hazard for the period of his working lifetime.*'' 29 U.S.C. § 655(b)(5) (emphasis added). The U.S. Court of Appeals for the District of Columbia upheld the use of a 45-year lifetime in the asbestos standard against an assertion by the Asbestos Information Association that the average duration of employment was five years. *Building and Construction Trades Department, AFL–CIO* v. *Brock*, 838 F.2d 1258, 1264, 1265 (D.C. Cir. 1988). The Court said that OSHA's assumption ''appears to conform to the intent of Congress'' as the standard must protect even the rare employee who would have 45 years of exposure. *Id.* at 1264. In addition, while working lifetimes will vary, risk is significant for some who work as little as one year and, at any rate, individual and population risks are likely to remain the same so long as employees who leave one job are replaced by others, and those who change jobs remain within a covered sector. Nevertheless, the Agency solicits information regarding the likelihood of exposure to active TB in the workplace and duration of employment in various occupational groups. Lifetime risk estimates of TB infection by state are described in section 4.

Lifetime risk estimates of developing active TB are calculated from lifetime risk estimates of TB infection assuming that, once infected, there is a 10% likelihood of progressing to active TB. These estimates are discussed in section 4. Further, the number of deaths caused by TB is calculated from the lifetime estimates of active TB using OSHA's estimate of TB case fatality rate, also discussed in section 4.

1. Definitions

For the purpose of estimating incidence rates, *TB infection* rate is defined as the annual probability of an individual converting from negative to positive in the tuberculin skin test. *Annual occupational* risk is defined as the annual excess risk of becoming infected with TB due to occupational exposure, and is estimated as a function of the background risk. *Lifetime occupational risk* is defined as the excess probability of becoming infected with TB due to exposure in the workplace, at least once, in the course of a 45-year working lifetime and is estimated as $\{1-(1-p)^{45}\}$ where p is the annual occupational risk of TB infection.

2. Data Sources for Estimating Occupational Risk

The quantitative data needed to develop an overall national estimate of risk for TB infection due to occupational exposure are not available. The CDC does not publish occupational data associated with TB infection incidence and active TB on a nationwide basis. There has been some effort to include occupational information on the TB reporting forms, but only a limited number of states are currently using the new forms that capture occupational information in a systematic way.

However, there are a number of sources that permit the risk in occupational settings to be reasonably estimated and, with the aid of mathematical models, to develop estimates of excess relative occupational risk (ERR_o), which can then be multiplied by the state-specific background rates to yield estimates of excess occupational risk. OSHA has identified three data sources that are suitable for assessing the excess risk of TB infection in health care workers with occupational exposure. These include: (1) A 1994 survey of tuberculin skin testing in all health care facilities in Washington State; (2) A state-wide survey of hospitals in North Carolina, conducted in 1984–1985, which addressed TB skin testing practices, TB infection prevalence, and TB infection incidence among hospital employees in that state; and (3) the employee tuberculin skin test conversion database from Jackson Memorial Hospital in Miami, Florida. In addition to these hospital employee data, the Agency has obtained data on selected other work groups from the state of Washington. These groups include workers employed in long-term health care, home health care, and home care.

On the issue of data availability for this risk assessment, Dr. Graham agrees with OSHA that there are no comprehensive data available with respect to occupational risk of TB infection in health care and other institutions in the U.S. Instead of relying on two state specific studies, Dr. Graham recommends, though with serious reservations, the use of a review study by Menzies et al. (Ex. 7–130). Dr. Graham admits that the ''validity of the estimates in these reports [reviewed in the Menzies et al. study] must be open to serious question * * *'' for the following reasons, which were pointed out by Dr. Graham: several of the studies reviewed are very old and not relevant to TB risk in the 1990s; four studies use tine tests and self-reports of skin test results, which are not useful for estimation of risk of TB infection; the studies were not consistent in the inclusion of high and low risk workers; two-step testing was not done; and the participation rates were extremely low or unreported in many of the studies included in this review.

OSHA has chosen not to rely on the Menzies et al. review study, because, in addition to Dr. Graham's reservations (which the Agency shares), OSHA is also concerned about the inclusion in the Menzies et al. review article of studies conducted outside the U.S. Factors known to affect the epidemiology of TB, such as environmental conditions, socio-economic status, and work practices, are expected to differ greatly from one country to another, and are not controlled for in the statistical analyses of these studies. For all of these reasons, the Agency has chosen to rely solely on U.S. studies for its quantitative risk estimations.

Estimates of excess risk due to occupational exposure are expressed as the percent increase above background based on relative risk estimates derived from occupational studies. Internal control groups provided estimates of background risk for the Washington state and Jackson Memorial data sets. In the absence of a suitable internal control group, the estimated annual state-wide TB infection rate, as calculated in Section 3, was used as the background rate in the North Carolina study.

(a) *Washington State Data:* Initially, OSHA relied on a three-year prospective study, conducted between 1982 and 1984 in the state of Washington, to derive an estimate of excess risk for TB infection as a result of occupational exposure (Ex. 7–42). OSHA received several objections to the use of this study. The study used hospitals with no known TB cases as ''controls'' based on the assumption that in those hospitals the risk of TB infection to employees may be the same as for the general population. Dr. Qaqish noted that this assumption is highly questionable and that the use of such controls is not appropriate. Dr. Graham and Dr. Qaqish pointed out that the published results did not include conversions identified through contact investigations, which

means that the conversion rate reported in that study was likely to be an underestimate of the true risk. In addition, the commenters noted that the study was designed to estimate the effectiveness of the TB screening program and may have produced skin testing results biased toward the null; the study is relatively old; and, the study was conducted prior to the AIDS epidemic and therefore the results may not be relevant to the occupational risk at present because the relationship between HIV and TB is not reflected in this study.

In an effort to respond to reviewers' comments, the Agency chose to update the analysis by relying on a data set of tuberculin skin testing results from a survey of the state's tuberculin skin testing program in 1994. This survey is conducted by the TB Control Office in the Washington State Health Department and it covers all hospitals in the state, as well as long-term care, home health care, and home care facilities. OSHA was given access to the database for the 1994 survey as well as data on conversions identified through contact investigations for the same year (Ex. 7–263). Table V–2 summarizes the results of the 1994 survey. Of the 335 health care establishments in the state of Washington, 273 responded to the survey, for an overall response rate of 81.5%. Of those, 76 were hospitals, 142 were long-term care, 47 were home health care, and 8 were home care facilities. Hospitals had the highest survey response rate (85%) and home health care had the lowest (77%). Every employee at risk for TB infection (i.e., who was known to be tuberculin skin test negative at the start of the study period) in the participating hospitals and long-term care facilities was given a tuberculin skin test, including administrators, housekeepers, business office staff, and all part-time employees. Testing in home health care facilities was generally confined to those nursing staff who had direct client contact. Employees in home care are those who provide services to patients in home health care and include food handlers, cleaning aides, personal care-givers, and some social workers.

TABLE V–2—WASHINGTON STATE 1994 SURVEY RESULTS

Type of facility	Number of [a] establishments	Number of skin tests	Number of conversions	Annual rate of TB conversion
Hospital	76 (85%)	39,290	50	1.27/1,000
Long-term Care	142 (81%)	11,332	111	9.80/1,000
Home Health Care	47 (77%)	2,172	11	5.06/1,000
Home Care	8 (80%)	537	1	1.86/1,000
Total	273 (81.5%)	53,331	173	3.24/1,000

[a] Numbers in parentheses are study response rates for each group.

The overall rate of skin test conversion for workers in the health care system in Washington State in 1994 was 3.24 per 1,000 employees tested. This is greater than a 4-fold increase from the estimated state-wide background rate of 0.69 per 1,000 at risk, as calculated in section 3. The annual rate of TB conversion ranged from 1.27 per 1,000 tested for hospital employees to 9.80 per 1,000 tested for long-term care employees.

The annual rate of 9.8 per 1,000 for long-term care employees probably reflects the high potential for exposure to undiagnosed active TB in those facilities. As a rule, long-term facilities in Washington State do not have AFB isolation rooms. Therefore, residents with no obvious TB symptoms but who might be infectious spend most of their time in open spaces exposing other residents and workers to infectious droplet nuclei. However, once a resident has been identified as a suspect TB patient, that person is transferred to a hospital until medically determined to be non-infectious.

Also, since employees who were 35 years of age or younger were not given a two-step test at hiring, and a high percentage of employees are foreign born and therefore most likely to have been vaccinated during childhood with the BCG vaccine, some of the conversions observed might be late boosting because of BCG. However, an almost two-fold increase in risk for long-term care workers even as compared to the significant excess risk among home health care workers clearly indicates that the risk of TB infection for workers in long-term care is high and not likely to be fully explained by late boosting. Beginning in 1995, two-step testing has been done on all new hires in Washington State. Thus, tuberculin skin testing data for 1995 are not expected to be influenced by possible late boosting; OSHA will place the 1995 data in the rulemaking record as they become available.

Hospital workers had the lowest overall rate of conversion (overall rate of 1.27 per 1,000). This, in part, can be attributed to the existence of extensive TB control measures in that environment in Washington State. Compliance with the CDC Guidelines and OSHA's TB Compliance Directive is quite high in Washington State because: (a) There is a strong emphasis on early identification of suspect TB patients; (b) there is a strong emphasis on employee training and regular tuberculin skin testing (although on a less-frequent basis than recommended in the Guidelines: All employees are tested at hire and annually thereafter); (c) the use of respirators is expected when entering an isolation room; and (d) all isolation rooms are under negative pressure, have UV lights, and exhaust to the outside. In addition, conversion data in hospitals are more likely to represent true TB infections than in the other health care settings, because hospitals are more likely to re-test converters in an effort to eliminate false-positive cases.

A more thorough analysis of the hospital data is presented in table V–3. Because the Washington State survey was not designed to compare exposed persons with matched controls who have had no exposure, several alternative definitions of an internal control (unexposed) group were used in analyzing this data set. Three different analyses, shown in table V–3, produced estimates of annual occupational infection rates ranging from 0.4 to 0.6 per 1,000 above control (i.e., ranging from a 47% to an 84% increase above control). In order to minimize the likelihood of contaminating the control group with persons having significant occupational exposure, OSHA defined the control group as workers in hospitals located in zero-TB counties and with no known TB patients. This analysis is summarized in table V–3 as Definition 1. If potential for occupational exposure is defined as

either working in a hospital in a county that has active TB or in a hospital that has had TB patients, then the annual risk due to occupational exposure is 47% above background. The excess annual risk due to occupational exposure appears to be approximately 60% above background, if workers in hospitals with a transfer-out policy for TB patients are considered to be the control group, shown as Definition 2 in table V–3. A 60% increase above background is not statistically significantly different from a 47% increase and therefore these two ''control'' groups can be viewed as producing ''statistically'' equivalent results. However, the Agency believes that Definition 1 is more appropriate, though the risk estimates are higher if the control group is defined based on Definition 2, because there is a higher likelihood of potential for exposure to a patient with undiagnosed TB under Definition 2 conditions. Comparisons of all hospital TST data to the state-wide estimate of TB infection rate resulted in an estimate of the annual excess occupational risk of approximately 84% above background, shown in table V–3 as Definition 3. Estimates of the annual and lifetime occupational risk of TB infection for the average health care worker in hospitals by state, extrapolated from this study and using Definition 1 as the control group, are presented and summarized in section 4.

TABLE V–3—WASHINGTON STATE DATA HOSPITAL PPD SKIN TESTING RESULTS

Definition of exposed and control groups	Sample size	Number of skin tests given	Number of conversions observed	Average conversion rate 1 [a]	Overall conversion rate 2 [b]	Relative risk	
						Rate 1	Rate 2
Definition 1							
Control: Hospitals in zero-TB counties and with no-known TB patients	16	1,142	1	0.477	0.8756	.....	.....
Exposed: Hospitals in counties reporting TB or having TB patients	60	38,148	49	1.523	1.28447	3.19	1.47
Definition 2							
Control: Hospitals that transfer out TB patients	35	3,645	3	0.498	0.823	.....	.....
Exposed: Hospitals with isolation rooms	41	35,645	47	1.989	1.3185	3.99	1.602
Definition 3							
Control: State-wide estimates of annual risk of infection	.....	.....	.....	[c]0.69	[c]0.69	.....	.....
Exposed: All PPD testing data	76	39,290	50	1.302	1.27	1.89	1.84

[a]Rate 1 is estimated as the arithmetic average of hospital specific conversion rates.
[b]Rate 2 is estimated as the ratio of the sum of all conversions reported divided by the total number of skin tests given within each group.
[c]Source: Table V–3(b), state-wide rate of infection.

Annual rates of excess risk due to occupational exposure were estimated for long-term care, home health care, and home care and are presented in Section 4. The same control group used in the hospital data analysis, Definition 1 (i.e., 0.876/1,000 workers at risk) was used to estimate the background risk among workers in long-term care, health care, and home care facilities and settings. Using 0.876 as the background infection rate for workers in these settings (a) provided a level of consistency among the Washington data analyses, and (b) resulted in a lower estimate of occupational risk for the non-hospital health care workplaces than would have resulted had the state-wide background risk estimate (i.e., 0.67/1,000 see Section 3) been used. When industry-specific risk data are used, there is approximately a 10-fold increase in annual risk for workers in long-term care, a 5-fold increase in annual risk for workers in home health care, and a 1-fold increase in annual risk for workers in home care (see Section 4).

Estimates of the range of annual and lifetime occupational risk for the average health care worker in long-term care, home health care, and home care by state, extrapolated from the Washington State study, are presented in Section 4.

(b) *North Carolina Study:* A state-wide survey of all hospitals in North Carolina (NC) was conducted in 1984–1985 (Ex. 7–7). The survey's questionnaire was designed to address three main areas of concern affecting hospital employees: (1) Tuberculin skin testing practices; (2) TB infection prevalence; and (3) TB infection incidence. The incidence of new infections among hospital personnel was assessed over a five-year period by reviewing tuberculin skin test conversion data during calendar years 1980 through 1984 and was calculated as the number of TB skin test conversions divided by the number of skin tests administered. (Since most employees were only given annual testing, the number of tests administered is a very close estimate of the total number of people tested within a year and thus can be used as the denominator in estimating infection incidence.) Only 56 out of 167 hospitals reported information on TB conversion rates (34% response rate). The authors estimated a state-wide TB infection rate of 11.9 per 1,000 per year for hospital employees in 1984 and a five-year mean annual infection rate of 11.4 per 1,000, with a range of 0-89 per 1000 employees at risk for TB infection. An analysis of the data by region (i.e., eastern, central, western) showed that the eastern region had consistently higher rates (with an average infection rate of 18.0 per 1,000) followed by the central region (7.0 per 1,000) and the western region (6.1 per 1000). Results of this study are shown in table V–4.

TABLE V–4—SKIN TEST CONVERSION RATES [a] NORTH CAROLINA HOSPITAL PERSONNEL [b]

Region	Year					
	1980	1981	1992	1993	1984	5-year mean
Eastern	19.3 (7)	30.8 (10)	17.7 (11)	11.2 (12)	15.7 (18)	18.0 (19)
Central	3.0 (6)	3.7 (8)	7.2 (13)	6.6 (23)	10.0 (25)	7.0 (29)
Western	1.9 (2)	13.5 (4)	5.3 (4)	4.1 (4)	7.2 (8)	6.1 (8)

[a] Conversion rates are expressed as number of conversions per 1,000 workers tested.
[b] In parentheses is the number of hospitals included in the study.

Use of this study's overall results for risk estimates was criticized by the peer reviewers because of design flaws in the study (e.g., high non-response rate, inconsistent skin testing practices, and limited two-step testing) and, most importantly, the presence of atypical mycobacteria (contributing to false positive results) in the eastern part of the state. Based on further input from Dr. Comstock, the Agency chose to rely on the study results from the western region only, because they are considered to be more representative of the ''true'' risk of infection and are expected to be less confounded by cross-reactions to atypical mycobacteria. Further, the Agency chose to rely on the conversion rate estimated for 1984 because it was the most recent data reported in the study. Therefore, the western region conversion rate of 7.2 per 1,000, estimated based on responses to the survey from eight hospitals in 1984, was used as an overall worker conversion rate. Further, the 1984 rate was adjusted by the percent decrease of active TB between 1984 and 1994 in North Carolina so that the final worker conversion rate for 1994 based on the western region rates reported in this study was estimated to be 5.98 (7.2 * 532/641 = 5.98) per 1,000 employees at risk for TB infection.

The North Carolina study did not have an internal control group to use as the basis for estimating excess risk due to occupational exposure because the conversion rates presented in this study were based on TST results for the entire hospital employee population. In the absence of an internal control group, the Agency used the estimated state-wide background rate of 1.20 per 1,000 as the background rate of infection for the western region in North Carolina (see Section 3) to estimate excess risk due to occupational exposure.[1] Based on this study, annual occupational risk is approximately four times greater than background [(5.98–1.2)/1.2 = 3.98]. Estimates of the annual and lifetime occupational risk of TB infection based on this study by state are presented in Section 4.

(c) *Jackson Memorial Hospital Study:* Jackson Memorial Hospital (JMH) is a 1500-bed general facility located in Miami, Florida, employing more than 8,000 employees. It is considered one of the busiest hospitals in the U.S. It is the primary public hospital for Dade County and the main teaching hospital for the University of Miami School of Medicine. JMH treats most of the TB and HIV cases in Dade County and, consequently, there is a higher likelihood of occupational exposure to TB in this facility than in the average hospital in the U.S. From March 1988 to September 1990, an outbreak of multidrug-resistant TB (MDR–TB) occurred among patients and an increased number of TST conversions was observed among health care workers on the HIV ward. This prompted a re-evaluation of the hospital's infection control practices and the installation of engineering controls to minimize exposure to TB. As part of the evaluation of the outbreak, NIOSH did a Health Hazard Evaluation and issued a report (Ex. 7–108). In addition, NIOSH conducted a retrospective cohort study of JMH to determine whether the risk of TB infection was significantly greater for health care workers who work on wards having patients with infectious TB than those who work on wards without TB patients.

For the data analysis of this study, ''potential for occupational exposure'' was defined based on whether an employee worked on a ward that had records of 15 or more positive cultures for pulmonary or laryngeal TB during 1988–1989. In other words, positive culture was taken as a surrogate for exposure to infectious TB. The authors restricted the ''exposed'' group to employees on wards with exposures to pulmonary or laryngeal TB because they intended to restrict the study to hospital workers with exposure to patients with the highest potential for being infectious. There were 37 wards at JMH that had submitted at least one positive culture during 1988–1989. Seven wards met the criteria of 15 or more and were therefore included in the ''exposed'' group. These were the medical intensive care unit, five medical wards, and the emergency room. The ''control'' group was defined as hospital workers assigned to wards with no TB patients (i.e., wards with no records of positive cultures during 1988–89). The ''control'' wards were post-partum, labor and delivery, newborn intensive care unit, newborn intermediate care unit, and well newborn unit. The results of this analysis are presented in Table V–5.

TABLE V–5—SKIN TEST CONVERSION RATES FOR HOSPITAL PERSONNEL AT JACKSON MEMORIAL HOSPITAL [a, b]

Year	Exposed group	Control group	Relative risk	95% confidence interval
1989	62.2 (13/209)	6.2 (2/324)	10.1	2.3—44.2

[1] Using the state-wide estimate of population risk as the background estimate of risk for this study most likely results in an underestimate of the true excess risk due to occupational exposure, because the true background estimate of risk for the western region in North Carolina is expected to be less than the state-wide estimate, which is influenced by the large number of infections found in the eastern region of that state.

TABLE V–5—SKIN TEST CONVERSION RATES FOR HOSPITAL PERSONNEL AT JACKSON MEMORIAL HOSPITAL [a, b]—Continued

Year	Exposed group	Control group	Relative risk	95% confidence interval
1990	75.5 (16/212)	6.5 (2/309)	11.7	2.7—50.2
1991	31.7 (6/189)	3.5 (1/282)	9.0	1.1—73.8

[a] Rates are expressed as number of conversions per 1,000 workers tested.
[b] Source: Ex. 7–108

Table V–5 shows a substantially elevated risk for those workers with potential exposure to patients with infectious TB. The relative risk ranges from 9 to 11.7 between 1989 and 1991 and is statistically significant for all of those years. This suggests that the excess risk due to occupational exposure is approximately 8-fold above background; this is an overall risk estimate that reflects the occupational risk of TB infection for JMH employees with patient contact, because this analysis included everyone tested in the ''exposed'' and ''control'' group, regardless of his or her specific job duties or length of patient contact.

An analysis of various occupational groups within this cohort showed that nurses and ward clerks in the ''exposed'' groups had the highest conversion rates: 182 and 156 conversions per 1,000 workers tested, respectively. Other studies have shown that health care workers who provide direct patient care are at greater risk for infection than workers who do not provide direct patient care. The high risk seen in ward clerks was unexpected since these workers are not involved in direct patient care. However, in the emergency room, the risk for TST conversion for the ward clerks was almost three times higher than for the nurses, 222 and 83 per 1,000, respectively. Ward clerks in the emergency room are responsible for clerical processing of patients after triage, handling specimens for the laboratory, and gathering clothing and valuables from admitted patients. During these interactions, there may have been less strict adherence to infection control measures, and this could explain the high conversion rate.

OSHA used the results from the 1991 analysis of the data in the JMH study to estimate occupational risk of TB infection in hospital workers with a relatively high likelihood of occupational exposure, for the following reasons: (a) 1991 represents the most recent year for which conversion data are available prior to the time when TB infection control measures were fully implemented at JMH; and (b) The higher conversion rates reported for 1990 and 1989 (75.5 and 62.2 per 1,000 respectively) may be atypical, i.e., they may to some extent reflect the effect of the outbreak and not the long-term occupational risk.

Based on the results of this study, OSHA estimates that the annual excess risk of TB infection due to occupational exposure is 7.95 times greater than background. Estimates of annual and lifetime occupational risk of TB infection for the average health care worker in hospitals by state, extrapolated from this study, are presented and summarized in section 4.

3. Estimation of Background Risk of TB Infection

OSHA's methodology for estimating population (background) TB infection rates relies on the assumption that TB infection occurring in an area can be expressed as a numerical function of active TB cases reported in the same area. If the likelihood of observing any infection in a population is minimal, then the likelihood of observing active disease diminishes. Conversely, the presence of active TB implies the presence of infection, since active disease can only progress from infection. Therefore, there is a functional relationship linking TB infections to active disease being observed in a particular area during a specified time period.

Peer reviewer comments on this assumption varied. Neil Graham states in his comment ''Although factors such as migration and distribution of the population may influence this relationship it seems probable that this assumption is largely correct and justifiable.'' (Ex. 7–271). On the other hand, Dr. Simone expresses concern over this assumption and states ''It is not necessarily true that a change in cases now reflects the risk of infection now.'' Dr. Qaqish demonstrates in his comment that the net effect of assuming a proportional relationship between the number of active cases and the number of new infections is to introduce a possible bias into the estimate of background risk of TB infection, although such a bias could work in either direction, i.e., toward increasing or decreasing the estimate of risk. Dr. Qaqish further states that in the absence of more ''relevant data,'' it is not possible to determine the actual net effect in magnitude and direction of the bias and ''without obtaining additional data, it would be impossible for the Agency to improve on the accuracy of the risk estimates * * *'' OSHA has considered all of the reviewer comments and is aware of the inherent uncertainty and the potential for bias associated with the use of this assumption; however, in the absence of the additional ''relevant'' data to which Dr. Qaqish refers, the Agency believes this approach to be justifiable.

In defining the model used to estimate the annual infection rates occurring in a geographical area based on data on active disease cases reported for the same area, infections progressing to active disease are assigned to one of three distinct groups: those occurring this year, last year, and in previous years.

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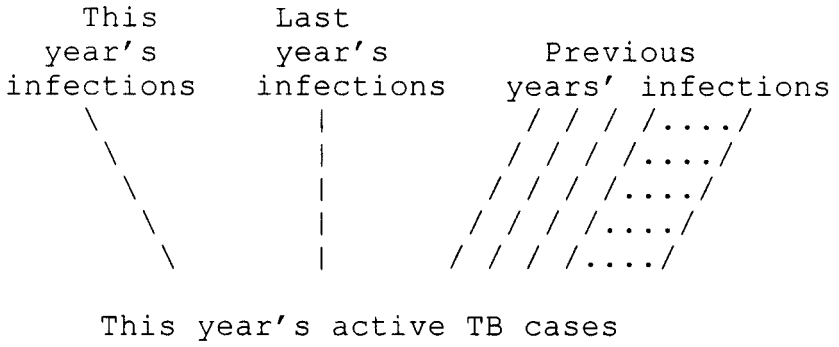

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TB cases reported to CDC each year are a combination of new and old infections that have, for various reasons, progressed to active disease. Until recently, it was believed that most of the active cases were the product of old infections. However, with the use of DNA fingerprinting techniques, researchers have reported that a larger percentage of active cases may be attributed to new or recent infections. Small *et al.* reported, in an article on tracing TB through DNA fingerprinting, that as many as 30% of the active cases reviewed in the study may be the result of recent infections (Ex. 7–196).

In this risk assessment, the Agency assumes the lifetime risk that an infection will progress to active TB to be approximately 10%. This estimate is supported by CDC and in her comment, Dr. Simone states that: ''The assumption * * * is generally agreed upon.'' Dr. Comstock and Dr. Qaqish both questioned the validity and accuracy of CDC's estimate. Their comments suggest that the true lifetime rate of progression from infection to active disease for adults may be less than 10 percent. However, as Dr. Graham points out, the 10% assumption is a widely accepted ''rule of thumb'' and is also in relative agreement with data from the unvaccinated control group of the British Medical Research Council (MRC) vaccination trial in adolescents (Ex. 7–266).

In the MRC study, 1,338 adolescents' skin tests converted following TB exposure where the precise date of conversion was known. Of these, 108 (8.1%) individuals developed active TB during follow-up. Of these, 54% developed active TB within one year and 78% within 2 years. This results in a risk of approximately 4% at one year, 6% at two years, and an overall risk of 8%. Given that the risk of TB reactivation increases with age, the lifetime risk is expected to be higher than the 8% attained in this study and, as Dr. Graham points out, a 10% overall lifetime risk seems reasonable.

Based on Dr. Graham's recommendation to rely on the progression rates from the MRC study, OSHA changed the assumption on the progression parameters from 2.5% (first year), 2.5% (second year), and 5% (remaining lifetime) to 4%, 2% and 4%, respectively. Therefore the total 10% progression from infection to active disease is partitioned into 3 groups: progression during the first year after infection (40% of all infections that eventually progress, for a net probability of 4%), progression during the second year (20% of all infections that eventually progress, for a net probability of 2%), and progression during all subsequent years (the remaining 40% of progressing infections). This last probability (4%) is assumed to be uniformly distributed across the remaining lifespan.

TB rates vary considerably by geographic area, socio-economic status, and other factors. In an attempt to account for some of those factors, to the extent possible, background TB infection rates have been estimated separately for each state. The derivation of background infection rates involves several steps for which the process and formulae are presented below.

Step 1: Background rate of TB infection for state i in year j is defined as:

$$B_{i(j)}=I_{i(j)}/X_{i(j)} \qquad (1)$$

where:

$B_{i(j)}$ is the background TB infection rate for state i in year j

$I_{i(j)}$ is an estimate of the number of new infections that occurred in state i in year j

$X_{i(j)}$ is the population at risk for TB infection in state i in year j.

Step 2: Estimation of $I_{i(j)}$, the number of new TB infections:

Let:

$A_{i(j)}$ be the total number of adult TB cases reported to CDC by state i in year j.

$A_{(j)}$ be the total number of adult TB cases reported to CDC by all states in year j.

$P_{i(j)}$ be the estimated prevalence of adult TB infection in state i during year j.

R_i be the ratio of the number of adult TB cases reported in 1993 to the number of adult cases reported in 1994 in state i.

The number of TB cases reported in 1994 can be expressed as a function of TB infections expected to have progressed to active disease, by the following formula:

$$A_{i(1994)}=.04*I_{i(1994)}+.02*I_{i(1993)}+(.04/73)*I_{i(1992)}*\text{prob(alive in 1994)}$$
$$+(.04/73)*I_{i(1991)}*\text{prob(alive in 1994)}$$
$$+....$$
$$+....$$
$$+(.04/73)*I_{i(1919)}*\text{prob(alive in 1994)}$$

This can be expressed as:

$$A_{i(1994)}=.04*I_{i(1994)}+.02*I_{i(1993)}+(.04/73)*\Sigma\,[I_{i(j)}*\text{prob(alive in 1994)}],$$

where j ranges from 1919 to 1992. The quantity inside the summation symbol is the sum of all people who were infected with TB between 1919 and 1992 and are still alive in 1994. This summation can be approximated by the prevalence of TB infection in 1992, $P_{i(1992)}$. Therefore, the number of active TB cases reported in 1994 can be expressed as:

$$A_{i(1994)}=.04*I_{i(1994)}+.02*I_{i(1993)}+(.04/73)*P_{i(1992)} \qquad (2)$$

Further, if we assume that the number of new infections is directly proportional to the number of active cases, then $I_{i(1993)}$ can be expressed as follows:

$$I_{i(1993)}=I_{i(1994)}*(A_{i(1993)}/A_{i(1994)}) \qquad (3)$$

and (2) can be expressed as:

$$A_{i(1994)}=[(.02*(A_{i(1993)}/A_{i(1994)})+.04]*I_{i(1994)}+(.04/73)*P_{i(1992)}$$
$$A_{i(1994)}=[(.02*R_i+.04]*I_{i(1994)}+(.04/73)*P_{i(1992)} \qquad (4)$$

then solving for $I_{i(1994)}$ becomes: [2]

[2] Using the prevalence of TB infection in 1992 (i.e., $P_{i(1992)}$) to approximate the quantity inside the summation sign (i.e., everyone infected between 1919 and 1992 and alive in 1994) slightly overestimates the quantity inside the summation (i.e., $P_{i(1992)}$ is slightly larger than the quantity it approximates.) It includes a small number of people

$I_{i(1994)}=[A_{i(1994)}-.04/73*P_{i(1992)}]/(.02*R_i+.04)$ (5)

Step 3: Estimation of $X_{i(1994)}$:

$X_{i(1994)}$, the population at risk for TB infection in state i in 1994, is estimated as follows:

$X_{i(1994)}=N_i-P_{i(1993)}$ (6)

Where:

N_i is the adult population for state i as reported by U.S. Census in 1994.

$P_{i(1993)}$ is the estimated number of infected adults in state i in 1993 (i.e., prevalence of TB infection in state i among adults).

To estimate the number of adults currently at risk for TB infection in each state, the number of already infected adults (i.e., prevalence of TB infection P_i in 1993) is subtracted from the adult population in 1994.

Step 4: Estimation of population currently infected as of 1993 by state, $P_i(1993)$:

The prevalence of TB infection in each state is estimated as a function of TB infection prevalence in the U.S. in 1993 and the percent TB case rate for each state.

$P_{i(1993)}=P_{(1993)}*(A_{i(1993)}/A_{(1993)})$ (7)

Where:

$P_{(1993)}$ is the prevalence of TB infections in the U.S. in 1993 (Ex. 7–66) and

$A_{(1993)}$ is the total number of adult TB cases reported in 1993.

Estimates of TB infection prevalence in the U.S. were developed for OSHA by Dr. Christopher Murray of the Harvard Center for Population and Development Studies and are presented in Table V–6 (Ex. 7–267). The mathematical model used by Dr. Murray to estimate TB infection prevalence has been designed to capture the transmission dynamics of TB by modeling transfers between a series of age-stratified compartments using a system of differential equations. The model adjusts for various epidemiological factors known to influence the course of active TB, such as onset of infection (i.e., old vs. new infections) and the impact of immigration rates and the HIV epidemic. However, it does not differentiate among gender or race categories. The model has been successfully validated using actual epidemiological data on active TB from 1965 to 1994. The estimates of TB prevalence rates presented here are specific for adults (i.e., older than 18 years of age), which make them more appropriate for estimating risk of transmission in an occupational setting.

TABLE V–6.—NATIONAL PREVALENCE OF TB INFECTION IN ADULTS (18+) [a] [b]

Year	Expected	Minimum	Maximum
1992	6.87% (12,978,461)	6.53% (12,336,150)	7.22% (13,639,663)
1993	6.64% (12,667,062)	6.31% (12,037,524)	6.97% (13,296,599)
1994	6.47% (12,449,445)	6.14% (11,814,465)	6.79% (13,065,182)

[a] Numbers in parentheses are population prevalence figures.
[b] Estimated for OSHA by Christopher Murray MD, PhD, Harvard University, Center for Population and Development Studies (Ex. 7–267).

To estimate the number of previously infected adults in each state (P_i), the estimated national TB prevalence figure was multiplied by the active cases for each state and divided by the total number of active cases reported [see equation (7)] (i.e., the national prevalence estimate was apportioned among the states based on each state's percent contribution to active TB reported for 1993). To estimate the number of adults at risk of TB infection, (X_i), the number of already infected adults was subtracted from the adult population estimate for each state (see equation (6)). The number of new infections expected to have occurred in 1994 was estimated using equation (5).

The background rate of TB infection for 1994 was then estimated by dividing the number of new infections (I_i) by the number of susceptible adults in each state (X_i) (see equation (1)).

Results on estimated TB background annual infection rates for each state are presented in Table V–7(a)—Table V–7(c). In Table V–7(a) TB infection rates are based on an average value of TB infection prevalence, as estimated by Dr. Murray, in the U.S. (i.e., 12,667,062). In Table V–7(b), infection rates are based on the minimum value of TB infection prevalence in the U.S. (i.e., 12,037,524). In Table V–7(c), infection rates are based on the maximum value of TB infection prevalence in the U.S. (i.e., 13,296,599). An overall range of background annual TB infection rates was constructed by combining all three sets of infection rates and was estimated to be between 0.194 and 3.542 per 1,000 individuals at risk of TB infection, with a weighted average of 1.46 per 1,000 using state population size as weights.

TABLE V–7(a).—ESTIMATES OF ANNUAL BACKGROUND TB INFECTION RATES [a]

[Referent Year 1994]

State	TB cases reported in 1994 A_i	Population size [a] N_i	Population currently infected [b] $P_{i(1993)}$	Population at risk X_i	Estimate of new infections I_i	Annual population rate of TB infection B_i
Alabama (01)	413	3,139	250,083	2,888,917	4,779	1.65
Alaska (02)	78	414	27,787	386,213	1,182	3.06
Arizona (04)	233	2,936	118,231	2,817,769	2,858	1.01
Arkansas (05)	235	1,813	107,334	1,705,666	2,906	1.70
California (06)	4,291	22,754	2,437,044	20,280,956	47,852	2.36

who were infected with TB and were alive as of 1992 and who were therefore included in the prevalence figure, but who died before 1994, and, technically, are not included in the summation. This implies that, in equation (5), a slightly larger number is being subtracted from $A_{i(1994)}$ than should be, resulting in an underestimate of the number of new infections in 1994 and an underestimate of the occupational risk.

TABLE V–7(a).—ESTIMATES OF ANNUAL BACKGROUND TB INFECTION RATES [a]—Continued

[Referent Year 1994]

State	TB cases reported in 1994 A_i	Population size [a] N_i	Population currently infected [b] $P_{i(1993)}$	Population at risk X_i	Estimate of new infections I_i	Annual population rate of TB infection B_i
Colorado (08)	90	2,686	52,850	2,633,150	1,045	0.40
Connecticut (09)	144	2,487	81,182	2,405,818	1,665	0.69
Delaware (10)	51	531	26,152	504,848	671	1.33
D.C. (11)	116	451	80,092	370,908	1,162	3.13
Florida (12)	1,675	10,691	846,687	9,844,314	20,545	2.09
Georgia (13)	676	5,162	396,646	4,765,354	7,082	1.49
Hawaii (15)	234	875	132,942	742,058	25,890	3.49
Illinois (17)	1,021	8,669	622,211	8,046,789	10,994	1.37
Indiana (18)	201	4,279	129,673	4,149,327	2,083	0.50
Iowa (19)	62	2,180	31,056	2,068,943	859	0.42
Kansas (20)	77	1,864	37,049	1,826,951	1,065	0.58
Kentucky (21)	316	2,857	203,227	2,653,773	3,273	1.23
Louisiana (22)	412	3,080	185,792	2,894,208	5,582	1.93
Maine (23)	31	934	14,712	919,289	419	0.46
Maryland (24)	344	3,743	211,399	3,531,601	3,582	1.01
Massachusetts (25)	299	4,617	183,067	4,433,933	2,889	0.65
Michigan (26)	438	6,971	246,269	6,724,731	5,036	0.75
Minnesota (27)	127	3,326	68,105	3,257,895	1,413	0.43
Mississippi (28)	262	1,913	141,659	1,771,341	3,120	1.76
Missouri (29)	241	3,899	128,583	3,770,417	2,922	0.78
Montana (30)	22	618	11,987	606,013	290	0.48
Nebraska (31)	22	1,181	12,531	1,168,469	233	0.20
Nevada (32)	111	1,181	50,670	1,130,330	1,514	1.34
New Hampshire (33)	17	845	13,076	831,924	182	0.22
New Jersey (34)	764	5,973	456,579	5,516,421	8,150	1.48
New Mexico (35)	78	1,156	35,415	1,120,585	944	0.84
New York (36)	3,414	13,658	2,044,797	11,613,203	34,728	2.99
North Carolina (37)	532	5,314	298,574	5,015,426	6,000	1.20
North Dakota (38)	10	466	3,813	426,186	132	0.29
Ohio (39)	318	8,248	161,274	8,086,726	3,763	0.47
Oklahoma (40)	231	2,378	101,886	2,276,114	3,064	1.35
Oregon (41)	146	2,303	78,457	2,224,543	1,793	0.81
Pennsylvania (42)	583	9,154	379,211	8,774,789	5,886	0.67
Rhode Island (44)	47	757	31,601	725,399	495	0.68
South Carolina (45)	362	2,712	205,406	2,506,594	4,273	1.70
South Dakota (46)	26	513	8,173	504,827	342	0.68
Tennessee (47)	494	3,878	283,863	3,594,137	5,759	1.60
Texas (48)	2,276	13,077	1,199,200	11,877,800	27,306	2.30
Utah (49)	47	1,236	23,973	1,212,027	427	0.35
Vermont (50)	10	434	2,724	431,276	160	0.37
Virginia (51)	330	4,949	226,110	4,722,890	3,220	0.68
Washington (53)	241	3,935	142,729	3,792,251	2,554	0.67
West Virginia (54)	80	1,393	40,318	1,352,682	919	0.68
Wisconsin (55)	104	3,735	50,126	3,684,874	1,307	0.35
Wyoming (56)	12	339	3,814	335,186	188	0.56

[a] Expressed in thousands.
[b] Based on 6.64% rate of TB infection prevalence in the U.S. (expected)

TABLE V–7(b).—Estimates of Annual Background TB Infection Rates

[Referent Year 1994 [a]]

State	TB cases reported in 1994 A_i	Population size [a] N_i	Population currently infected [b] $P_i(1993)$	Population at risk X_i	Estimate of new infections I_i	Annual population rate of TB infection B_i
Alabama (01)	413	3,139	237,654	2,901,346	4,871	1.68
Alaska (02)	78	414	26,406	387,594	1,196	3.09
Arizona (04)	233	2,936	112,355	2,823,645	2,913	1.03
Arkansas (05)	235	1,813	102,000	1,711,000	2,967	1.73
California (06)	4,291	22,754	2,350,136	20,403,864	48,956	2.40
Colorado (08)	90	2,686	50,223	2,635,777	1,066	0.40
Connecticut (09)	144	2,487	77,147	2,409,853	1,700	0.71
Delaware (10)	51	531	24,853	506,147	681	1.34
D.C. (11)	116	451	76,111	374,889	1,192	3.18

TABLE V–7(b).—Estimates of Annual Background TB Infection Rates—Continued

[Referent Year 1994 [a]]

State	TB cases reported in 1994 A_i	Population size [a] N_i	Population currently infected [b] P_i(1993)	Population at risk X_i	Estimate of new infections I_i	Annual population rate of TB infection B_i
Florida (12)	1,675	10,691	804,607	9,886,393	20,944	2.12
Georgia (13)	676	5,162	376,933	4,785,067	7,275	1.52
Hawaii (15)	234	875	126,335	748,665	2,652	3.54
Illinois (17)	1,021	8,669	591,288	8,077,712	11,260	1.39
Indiana (18)	201	4,279	123,228	4,155,772	2,136	0.51
Iowa (19)	62	2,180	29,513	2,070,487	869	0.42
Kansas (20)	77	1,864	35,208	1,828,792	1,079	0.59
Kentucky (21)	316	2,857	193,126	2,663,874	3,357	1.26
Louisiana (22)	412	3,080	176,558	2,903,442	5,667	1.95
Maine (23)	31	934	13,980	920,020	425	0.46
Maryland (24)	344	3,743	200,893	3,542,107	3,677	1.04
Massachusetts (25)	299	4,617	173,969	4,443,031	2,983	0.67
Michigan (26) ,	438	6,971	234,030	6,736,970	5,144	0.76
Minnesota (27)	127	3,326	64,721	3,261,279	1,448	0.44
Mississippi (28)	262	1,913	134,619	1,778,381	3,183	1.79
Missouri (29)	241	3,899	122,193	3,776,807	2,978	0.79
Montana (30)	22	618	11,391	606,609	294	0.48
Nebraska (31)	22	1,181	11,909	1,169,091	240	0.21
Nevada (32)	111	1,181	48,152	1,132,848	1,536	1.36
New Hampshire (33)	17	845	12,426	832,574	185	0.22
New Jersey (34)	764	5,973	433,887	5,539,113	8,357	1.51
New Mexico (35)	78	1,156	33,655	1,112,345	965	0.86
New York (36)	3,414	13,658	1,943,173	11,714,827	35,735	3.05
North Carolina (37)	532	5,314	283,735	5,030,265	6,138	1.22
North Dakota (38)	10	466	3,624	462,376	134	0.29
Ohio (39)	318	8,248	153,259	8,094,741	3,845	0.48
Oklahoma (40)	231	2,378	96,822	2,281,178	3,116	1.37
Oregon (41)	146	2,303	74,558	2,228,442	1,825	0.82
Pennsylvania (42)	583	9,154	360,365	8,793,635	6,047	0.69
Rhode Island (44)	47	757	30,030	726,970	506	0.70
South Carolina (45)	362	2,712	195,197	2,516,803	4,356	1.73
South Dakota (46)	26	513	7,766	505,234	350	0.69
Tennessee (47)	494	3,878	269,756	3,608,244	5,875	1.63
Texas (48)	2,276	13,077	1,139,601	11,937,399	27,853	2.33
Utah (49)	47	1,236	22,782	1,213,218	446	0.37
Vermont (50)	10	434	2,589	431,411	162	0.37
Virginia (51)	330	4,949	214,873	4,734,127	3,311	0.70
Washington (53)	241	3,935	135,654	3,799,346	2,621	0.69
West Virginia (54)	80	1,393	38,315	1,354,685	941	0.69
Wisconsin (55)	104	3,735	47,634	3,687,366	1,332	0.36
Wyoming (56)	12	339	3,624	335,376	190	0.57

[a] Expressed in thousands.
[b] Based on a 6.31% rate of TB infection in the U.S.

TABLE V–7(c).—ESTIMATES OF ANNUAL BACKGROUND TB INFECTION RATES

[Referent Year 1994 [a]]

State	TB cases reported in 1994 A_i	Population size N_i	Population currently infected [b] P_i (1993)	Population at risk X_i	Estimate of new infections I_i	Annual population rate of TB infection, B_i
Alabama (01)	413	3,139	262,512	2,876,488	4,685	1.63
Alaska (02)	78	414	29,168	384,832	1,167	3.03
Arizona (04)	233	2,936	124,107	2,811,893	2,801	1.00
Arkansas (05)	235	1,813	112,669	1,700,332	2,843	1.67
California (06)	4,291	22,754	2,595,951	20,158,049	46,720	2.32
Colorado (08)	90	2,686	55,476	2,630,524	1,024	0.39
Connecticut (09)	144	2,487	85,216	2,401,784	1,629	0.68
Delaware (10)	51	531	27,452	503,508	661	1.31
D.C.	116	451	84,072	366,928	1,131	3.08
Florida (12)	1,675	10,691	888,766	9,802,234	20,137	2.05
Georgia (13)	676	5,162	416,359	4,745,641	6,884	1.45
Hawaii (15)	234	875	139,539	735,451	2,526	3.43
Illinois (17)	1,021	8,669	653,134	8,015,866	10,721	1.34

TABLE V–7(c).—ESTIMATES OF ANNUAL BACKGROUND TB INFECTION RATES—Continued

[Referent Year 1994 [a]]

State	TB cases reported in 1994 A_i	Population size N_i	Population currently infected [b] P_i (1993)	Population at risk X_i	Estimate of new infections I_i	Annual population rate of TB infection, B_i
Indiana (18)	201	4,279	136,117	4,142,883	2,029	0.49
Iowa (19)	62	2,180	32,600	2,067,401	849	0.41
Kansas (20)	77	1,864	38,891	1,825,109	1,052	0.58
Kentucky (21)	316	2,857	213,327	2,643,673	3,187	1.21
Louisiana (22)	412	3,080	195,025	2,884,975	5,496	1.91
Maine (23)	31	934	15,442	918,558	413	0.45
Maryland (24)	344	3,743	221,905	3,521,095	3,484	0.99
Massachusetts (25)	299	4,617	192,166	4,424,834	2,793	0.63
Michigan (26)	438	6,971	258,508	6,712,492	4,925	0.73
Minnesota (27)	127	3,326	71,490	3,254,510	1′,377	0.42
Mississippi (28)	262	1,913	148,700	1,764,300	3,057	1.73
Missouri (29)	241	3,899	134,973	3,764,027	2,865	0.76
Montana (30)	22	618	12,582	605,418	286	0.48
Nebraska (31)	22	1,181	13,154	1,167,846	227	0.20
Nevada (32)	111	1,181	53,189	1,127,811	1,491	1.32
New Hampshire (33)	17	845	13,726	831,274	178	0.21
New Jersey (34)	764	5,973	479,270	5,493,730	7,938	1.44
New Mexico (35)	78	1,156	37,175	1,118,825	922	0.82
New York (36)	3,414	13,658	2,146,421	11,511,421	33,696	2.92
North Carolina (37)	532	5,314	313,413	5,000,587	5,859	1.17
North Dakota (38)	10	466	4,003	461,997	129	0.28
Ohio (39)	318	8,248	169,289	8,078,711	3,678	0.46
Oklahoma (40)	231	2,378	106,949	2,271,051	3,011	1.33
Oregon (41)	146	2,303	82,357	2,220,643	1,760	0.80
Pennsylvania (42)	583	9,154	398,057	8,755,943	5,722	0.66
Rhode Island (44)	47	757	33,171	723,829	483	0.67
South Carolina (45)	362	2,712	215,614	2,496,386	4,188	1.68
South Dakota (46)	26	513	8,579	504,421	334	0.67
Tennessee (47)	494	3,878	297,971	3,580,029	5,641	1.58
Texas (48)	2,276	13,077	1,258,799	11,818,201	26,746	2.26
Utah (49)	47	1,236	25,165	1,210,835	408	0.34
Vermont (50)	10	434	2,860	431,140	158	0.37
Virginia (51)	330	4,949	237,347	4,711,653	3,126	0.66
Washington (53)	241	3,935	149,843	3,785,157	2,485	0.66
West Virginia (54)	80	1,393	42,322	1,350,679	896	0.66
Wisconsin (55)	104	3,735	52,617	3,682,383	1,283	0.35
Wyoming (56)	12	339	4,003	334,997	185	0.55

[a] Expressed in thousands.
[b] Based on 6.97% rate of TB infection prevalence in the U.S. (maximum estimate).

Step 5 Model validation:

An alternative, but less sophisticated, way to estimate annual risk of infection, if prevalence is known in a specific age group, is to use the following formula:

Annual Rate of Infection = -ln(1-P)/d (8)

Where:

P is the percent prevalence of infection and

d is the average age of the population (Ex. 7–265).

In order to validate the model used by OSHA to estimate background infection rates, estimates of TB infection prevalence for 1994 were used to calculate predicted infection rates using equation (8). Based on Murray's model, TB infection prevalence is expected to range from 6.31% to 6.97% in 1994 among adults (18+). Using these figures and assuming the average age to be 45 years, formula (8) predicts that infection rates can range from 1.45 to 1.61 per 1,000. These results are in close agreement with OSHA's weighted average estimate of the national TB infection rate, which is 1.46 per 1,000.

4. Occupational Risk Estimations

OSHA used the three different data sources to obtain estimates of risk of TB infection for health care employees: the Washington State data, the North Carolina study, and the NIOSH Health Hazard Evaluation (HHE) from Jackson Memorial Hospital (Exs. 7–263, 7–7, 7–108). The Washington State data represent workplaces located in low TB prevalence areas, where TB infection control measures and engineering controls are required by state health regulations. The North Carolina data represent workplaces located in areas with moderate TB prevalence and inadequate TB infection control programs. Finally, the Jackson Memorial Hospital data are representative of county hospitals serving high-risk patients whose employees have a high frequency of exposure to infectious TB. These data sources provide information on the magnitude of the expected excess risk in three different environments, and are used to provide a range of possible values of excess risk.

Based on the Washington State data, the annual risk is expected to be 1.5 times the background rate for hospital employees, approximately 11 times the background rate for long-term care employees, 6 times the background rate for home health care workers, and double the background rate for home care employees. Based on the North Carolina data, the annual risk is

expected to be approximately 5 times the background rate. Based on the Jackson Memorial Hospital data, the annual risk is expected to be approximately 9 times the background.

Estimates of expected excess risk of TB infection for workers with occupational exposure by state are calculated by applying the excess relative risk ratios, derived from the three occupational studies, to the overall background rate of infection for each state and are presented in table V–8(a)—table V–8(c). A range of excess risk of TB infection due to occupational exposure is constructed by using the minimum and maximum estimates of excess risk among all states for each data source. These results are presented in table V–9 and table V–10 for workers in hospitals and for workers in other work settings, respectively.

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TABLE V-8(a)
Occupational Risk Estimates of TB Infection
Based on the Washington State Study

State	Annual Background TB Infection Rate per 1,000 at Risk	Excess Occupational Risk	
		Annual	Lifetime
Alabama (01)	1.63 - 1.68	0.77 - 0.79	34 - 35
Alaska (02)	3.03 - 3.09	1.43 - 1.45	62 - 63
Arizona (04)	1.00 - 1.03	0.47 - 0.48	21 - 22
Arkansas (05)	1.67 - 1.73	0.79 - 0.81	35 - 36
California (06)	2.32 - 2.40	1.09 - 1.13	48 - 50
Colorado (08)	0.39 - 0.40	0.18 - 0.19	8 - 9
Connecticut (09)	0.68 - 0.71	0.32 - 0.33	14 - 15
Delaware (10)	1.31 - 1.34	0.62 - 0.63	27 - 28
District of Columbia (11)	3.08 - 3.18	1.45 - 1.49	63 - 65
Florida (12)	2.05 - 2.11	0.97 - 1.00	43 - 44
Georgia (13)	1.45 - 1.52	0.68 - 0.71	30 - 32
Hawaii (15)	3.43 - 3.54	1.61 - 1.66	70 - 72
Illinois (17)	1.34 - 1.39	0.63 - 0.66	28 - 29
Indiana (18)	0.50 - 0.51	0.23 - 0.24	10 - 11
Iowa (19)	0.41 - 0.42	0.19 - 0.20	9 - 9
Kansas (20)	0.58 - 0.59	0.27 - 0.28	12 - 12
Kentucky (21)	1.21 - 1.26	0.57 - 0.59	25 - 26
Louisiana (22)	1.91 - 1.95	0.90 - 0.92	39 - 40
Maine (23)	0.45 - 0.46	0.21 - 0.22	9 - 10
Maryland (24)	0.99 - 1.04	0.46 - 0.49	21 - 22
Massachusetts (25)	0.63 - 0.67	0.30 - 0.32	13 - 14
Michigan (26)	0.73 - 0.76	0.34 - 0.36	15 - 16
Minnesota (27)	0.42 - 0.44	0.20 - 0.21	9 - 9
Mississippi (28)	1.73 - 1.79	0.81 - 0.84	36 - 37
Missouri (29)	0.76 - 0.79	0.36 - 0.37	16 - 17
Montana (30)	0.47 - 0.48	0.22 - 0.23	10 - 10
Nebraska (31)	0.19 - 0.20	0.09 - 0.10	4 - 4
Nevada (32)	1.32 - 1.35	0.62 - 0.64	27 - 28
New Hampshire (33)	0.21 - 0.22	0.10 - 0.10	5 - 7
New Jersey (34)	1.44 - 1.51	0.68 - 0.71	30 - 31
New Mexico (35)	0.82 - 0.86	0.39 - 0.40	17 - 18
New York (36)	2.93 - 3.05	1.38 - 1.43	60 - 63
North Carolina (37)	1.17 - 1.22	0.55 - 0.57	24 - 25
North Dakota (38)	0.28 - 0.29	0.13 - 0.13	6 - 6
Ohio (39)	0.46 - 0.48	0.21 - 0.22	9 - 10
Oklahoma (40)	1.33 - 1.36	0.62 - 0.64	9 - 10
Oregon (41)	0.79 - 0.82	0.37 - 0.38	17 - 17
Pennsylvania (42)	0.65 - 0.69	0.31 - 0.32	14 - 14
Rhode Island (44)	0.67 - 0.70	0.31 - 0.33	14 - 15
South Carolina (45)	1.68 - 1.73	0.79 - 0.81	35 - 36
South Dakota (46)	0.66 - 0.69	0.31 - 0.33	14 - 15
Tennessee (47)	1.58 - 1.63	0.74 - 0.77	33 - 34
Texas (48)	2.26 - 2.33	1.06 - 1.10	47 - 48
Utah (49)	0.34 - 0.37	0.16 - 0.17	7 - 8
Vermont (50)	0.36 - 0.37	0.17 - 0.18	8 - 8
Virginia (51)	0.66 - 0.70	0.31 - 0.33	14 - 15
Washington (53)	0.66 - 0.69	0.31 - 0.32	14 - 14
West Virginia (54)	0.66 - 0.70	0.31 - 0.33	14 - 15
Wisconsin (55)	0.35 - 0.36	0.16 - 0.17	7 - 8
Wyoming (56)	0.55 - 0.57	0.26 - 0.27	12 - 12

TABLE V-8(b)
Occupational Risk Estimates of TB Infection
Based on the North Carolina Study

State	Annual Background TB Infection Rate per 1,000 at Risk	Excess Occupational Risk	
		Annual	Lifetime
Alabama (01)	1.63 - 1.68	6.48 - 6.68	254 - 260
Alaska (02)	3.03 - 3.09	12.07 - 12.28	421 - 427
Arizona (04)	1.00 - 1.03	3.97 - 4.11	164 - 169
Arkansas (05)	1.67 - 1.73	6.66 - 6.90	260 - 268
California (06)	2.32 - 2.40	9.22 - 9.55	341 - 351
Colorado (08)	0.39 - 0.40	1.55 - 1.61	67 - 70
Connecticut (09)	0.68 - 0.71	2.70 - 2.81	115 - 119
Delaware (10)	1.31 - 1.34	5.23 - 5.35	210 - 215
District of Columbia (11)	3.08 - 3.18	12.27 - 12.66	426 - 436
Florida (12)	2.05 - 2.11	8.18 - 8.43	309 - 317
Georgia (13)	1.45 - 1.52	5.77 - 6.05	229 - 239
Hawaii (15)	3.43 - 3.54	13.67 - 14.10	462 - 472
Illinois (17)	1.34 - 1.39	5.32 - 5.55	214 - 221
Indiana (18)	0.50 - 0.51	1.95 - 2.05	84 - 88
Iowa (19)	0.41 - 0.42	1.64 - 1.67	71 - 73
Kansas (20)	0.58 - 0.59	2.29 - 2.35	98 - 100
Kentucky (21)	1.21 - 1.26	4.80 - 5.02	195 - 202
Louisiana (22)	1.91 - 1.95	7.58 - 7.77	290 - 296
Maine (23)	0.45 - 0.46	1.79 - 1.84	77 - 80
Maryland (24)	0.99 - 1.04	3.94 - 4.13	163 - 170
Massachusetts (25)	0.63 - 0.67	2.51 - 2.67	107 - 113
Michigan (26)	0.73 - 0.76	2.92 - 3.04	123 - 128
Minnesota (27)	0.42 - 0.44	1.68 - 1.77	73 - 77
Mississippi (28)	1.73 - 1.79	6.90 - 7.12	268 - 275
Missouri (29)	0.76 - 0.79	3.03 - 3.14	128 - 132
Montana (30)	0.47 - 0.48	1.88 - 1.93	81 - 83
Nebraska (31)	0.19 - 0.20	0.77 - 0.82	34 - 36
Nevada (32)	1.32 - 1.35	5.26 - 5.40	211 - 216
New Hampshire (33)	0.21 - 0.22	0.85 - 0.88	38 - 39
New Jersey (34)	1.44 - 1.51	5.75 - 6.01	229 - 237
New Mexico (35)	0.82 - 0.86	3.28 - 3.42	137 - 143
New York (36)	2.93 - 3.05	11.65 - 12.14	410 - 423
North Carolina (37)	1.17 - 1.22	4.66 - 4.86	190 - 196
North Dakota (38)	0.28 - 0.29	1.11 - 1.16	49 - 50
Ohio (39)	0.46 - 0.48	1.81 - 1.89	78 - 82
Oklahoma (40)	1.33 - 1.36	5.28 - 5.44	212 - 216
Oregon (41)	0.79 - 0.82	3.15 - 3.26	133 - 137
Pennsylvania (42)	0.65 - 0.69	2.60 - 2.74	111 - 116
Rhode Island (44)	0.67 - 070	2.66 - 2.77	113 - 117
South Carolina (45)	1.68 - 1.73	6.68 - 6.89	260 - 267
South Dakota (46)	0.66 - 0.69	2.64 - 2.76	112 - 117
Tennessee (47)	1.58 - 1.63	6.27 - 6.48	247 - 254
Texas (48)	2.26 - 2.33	9.01 - 9.29	334 - 343
Utah (49)	0.34 - 0.37	1.34 - 1.46	59 - 64
Vermont (50)	0.36 - 0.37	1.46 - 1.49	63- -65
Virginia (51)	0.66 - 0.70	2.64 - 2.78	112 - 118
Washington (53)	0.66 - 0.69	2.61 - 2.75	111 - 116
West Virginia (54)	0.66 - 0.70	2.64 - 2.77	112 - 117
Wisconsin (55)	0.35 - 0.36	1.39 - 1.44	61 - 63
Wyoming (56)	0.55 - 0.57	2.20 - 2.25	94 - 97

TABLE V-8(c)
Occupational Risk Estimates of TB Infection
Based on the Jackson Memorial Hospital Study

State	Annual Background TB Infection Rate per 1,000 at Risk	Excess Occupational Risk	
		Annual	Lifetime
Alabama (01)	1.63 - 1.68	13.33 - 13.75	454 - 464
Alaska (02)	3.03 - 3.09	24.84 - 25.27	678 - 684
Arizona (04)	1.00 - 1.03	8.16 - 8.45	308 - 317
Arkansas (05)	1.67 - 1.73	13.69 - 14.20	462 - 475
California (06)	2.32 - 2.40	18.98 - 19.66	578 - 591
Colorado (08)	0.39 - 0.40	3.19 - 3.31	134 - 139
Connecticut (09)	0.68 - 0.70	5.55 - 5.78	222 - 230
Delaware (10)	1.31 - 1.34	10.75 - 11.01	385 - 392
District of Columbia (11)	3.08 - 3.18	25.24 - 26.04	683 - 695
Florida (12)	2.05 - 2.11	16.83 - 17.35	534 - 545
Georgia (13)	1.45 - 1.52	11.88 - 12.45	416 - 431
Hawaii (15)	3.43 - 3.54	28.13 - 29.01	723 - 734
Illinois (17)	1.34 - 1.39	10.95 - 11.42	391 - 404
Indiana (18)	0.50 - 0.51	4.01 - 4.21	165 - 173
Iowa (19)	0.41 - 0.42	3.36 - 3.44	141 - 144
Kansas (20)	0.58 - 0.59	4.72 - 4.83	192 - 196
Kentucky (21)	1.21 - 1.26	9.87 - 10.32	360 - 373
Louisiana (22)	1.91 - 1.95	15.60 - 15.99	507 - 516
Maine (23)	0.45 - 0.46	3.69 - 3.79	153 - 157
Maryland (24)	0.99 - 1.04	8.11 - 8.50	307 - 319
Massachusetts (25)	0.63 - 0.67	5.17 - 5.50	208 - 220
Michigan (26)	0.73 - 0.76	6.01 - 6.25	238 - 246
Minnesota (27)	0.42 - 0.44	3.46 - 3.64	145 - 151
Mississippi (28)	1.73 - 1.79	14.19 - 14.66	474 - 485
Missouri (29)	0.76 - 0.79	6.23 - 6.46	245 - 253
Montana (30)	0.47 - 0.48	3.87 - 3.96	160 - 164
Nebraska (31)	0.19 - 0.20	1.59 - 1.68	69 - 73
Nevada (32)	1.32 - 1.35	10.83 - 11.10	387 - 395
New Hampshire (33)	0.21 - 0.22	1.76 - 1.82	76 - 79
New Jersey (34)	1.44 - 1.51	11.83 - 12.36	415 - 429
New Mexico (35)	0.82 - 0.86	6.75 - 7.05	263 - 273
New York (36)	2.93 - 3.05	23.97 - 24.98	664 - 680
North Carolina (37)	1.17 - 1.22	9.60 - 9.99	352 - 364
North Dakota (38)	0.28 - 0.29	2.29 - 2.38	98 - 102
Ohio (39)	0.46 - 0.48	3.73 - 3.89	155 - 161
Oklahoma (40)	1.33 - 1.36	10.86 - 11.19	388 - 397
Oregon (41)	0.79 - 0.82	6.49 - 6.71	254 - 261
Pennsylvania (42)	0.65 - 0.69	5.35 - 5.63	214 - 224
Rhode Island (44)	0.67 - 0.70	5.47 - 5.70	218 - 227
South Carolina (45)	1.68 - 1.73	13.74 - 14.18	463 - 474
South Dakota (46)	0.66 - 0.69	5.42 - 5.68	217 - 226
Tennessee (47)	1.58 - 1.63	12.91 - 13.33	443 - 453
Texas (48)	2.26 - 2.33	18.54 - 19.10	569 - 580
Utah (49)	0.34 - 0.37	2.76 - 3.01	117 - 127
Vermont (50)	0.36 - 0.37	2.99 - 3.07	126 - 129
Virginia (51)	0.66 - 0.70	5.43 - 5.73	217 - 228
Washington (53)	0.66 - 0.69	5.38 - 5.65	215 - 225
West Virginia (54)	0.66 - 0.70	5.44 - 5.70	217 - 226
Wisconsin (55)	0.35 - 0.36	2.86 - 2.96	121 - 125
Wyoming (56)	0.55 - 0.57	4.53 - 4.64	185 - 189

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TABLE V–9.—OCCUPATIONAL RISK ESTIMATES FOR HOSPITAL EMPLOYEES [a]

Source	Overall risk/ (exposed)	Background risk based on study	Excess risk based on study (percent)	Range of excess occupational risk [d]	
				Annual	Lifetime
Washington State 1994 data	1.24/1000	0.88/1000	47	0.09–1.66	4.1–72.2
North Carolina Western Counties	[b] 5.98/1000	[d] 1.20/1000	398	0.77–14.1	34.2–472
Jackson Memorial (1991)	31.7/1000	3.5/1000	795	1.54–28.2	67.1–723

[a] Background TB infection rate ranges from 0.194 to 3.542 per 1,000 at risk for TB infection.
[b] Ajusted for 1994, i.e., 5.98=7.2*(532/641)
[c] The range reflects regional differences in TB prevalence as well as inherent uncertainty in the estimate of TB infection prevalence in the U.S., as estimated by Dr. Christopher Murray, and used in the internal calculations of annual background TB infection rate.
[d] State-wide estimate of population risk for North Carolina, shown in Table V–3(a).

TABLE V–10.—OCCUPATIONAL RISK ESTIMATES FOR OTHER WORK SETTINGS [a,b]

Type	Overall risk/ (exposed)	Background risk State-wide [c]	Excess risk based on study (percent)	Range of excess occupational risk [d]	
				Annual	Lifetime
Long-term Care	9.8/1000	0.8756/1000	1019	1.98–36.1	85–807
Home Health Care	5.06/1000	0.8756/1000	478	0.93–16.9	40.9–526
Home Care	1.86/1000	0.8756/1000	112	0.22–3.97	9.7–164

[a] Background TB infection rate ranges from 0.194 to 3.542 per 1,000 employees at risk of infection.
[b] Based on the Washington State data.
[c] Background rate for this analysis is assumed to be the same as in the case-control analysis of the Washington State hospital data (i.e. 0.8756 per 1,000 employees).
[d] The range reflects regional differences in TB prevalence as well as inherent uncertainty in the estimate of TB infection prevalence in the U.S., as estimated by Dr. Christopher Murray, and used in the internal calculations of annual background TB infection rate.

Lifetime estimates of the excess risk of TB infection were estimated based on the annual excess risk by using the formula $\{1–(1–p)^{45}\}$, where p is the annual excess risk. Lifetime excess estimates of TB infection are presented in table V–9 and table V–10. Lifetime risk estimates of developing active TB are calculated from lifetime risk estimates of TB infection assuming that, once infected, there is a 10% likelihood of progressing to active TB; these estimates are presented in table V–11 and table V–12. Further, the risk of death caused by TB is calculated from the lifetime estimates of active TB using OSHA's estimate of the TB case fatality rate (also presented in table V–11 and table V–12). The methodology used to estimate a TB case fatality rate is presented below.

TABLE V–11.—LIFETIME OCCUPATIONAL RISK ESTIMATES FOR HOSPITAL EMPLOYEES [a b c]

Source	TB infection [d]	Active disease [e]	Death caused by TB
Washington State (1994)	4.1–72.2	0.4–7.2	0.03–0.6
North Carolina Western Region	34.2–472	3.4–47.2	0.3–3.7
Jackson Memorial Hospital (Miami)	67.1–723	6.7–72.3	0.5–5.6

[a] Risk estimates reflect excess risk due to occupational exposure and are expressed per 1,000 employees at risk.
[b] Estimates of death caused by TB due to occupational exposure are derived based on an estimated TB case death rate of 77.85 per 1,000 TB cases and are estimated by multiplying the lifetime active disease rate by .07785.
[c] The ranges of risk presented in this TABLE reflect expected variance in the annual background TB infection rate by state. They are estimated based on the assumption that the annual background TB infection rate ranges from 0.194 to 1.542 per 1,000 employees at risk.
[d] Lifetime infection rate is estimated by $(1–(1–p)^{45})$, where p is the annual excess TB infection rate due to occupational exposure.
[e] Lifetime active disease rate is estimated to be 10% of lifetime infection rate.

TABLE V–12—LIFETIME OCCUPATIONAL RISK ESTIMATES FOR EMPLOYEES IN OTHER WORK SETTINGS [a b c]

Work setting	TB infection [d]	Active disease [e]	Death caused by TB
Long-term Care	85–807	8.5–80.7	0.7–6.2
Home Health Care	40.9–536	4.1–53.6	0.3–4.2
Home Care	9.7–164	1.0–16.4	0.1–1.3

[a] Risk estimates reflect excess risk due to occupational exposure and are expressed per 1,000 employees at risk of TB infection.
[b] Estimates of death caused by TB due to occupational exposure are derived based on an estimated TB case death rate of 77.85 per 1,000 cases and are estimated by multiplying the lifetime active disease rate by .07785.
[c] The ranges of risk presented in this TABLE reflect expected variance in the annual background TB infection rate by state. They are estimated based on the assumption that the annual background TB infection rate ranges from 0.194 to 3.542 per 1,000 employees at risk.
[d] Lifetime infection rate is estimated by $(1–(1–p)^{45})$, where p is the annual excess TB infection rate due to occupational exposure.
[e] Lifetime active disease rate is estimated to be 10% of lifetime infection rate.

As outlined in the Health Effects section, several possible outcomes are possible following an infection. Approximately 90% of all infections never progress to active disease. An estimated 10% of infections is expected to progress to active disease; most of these cases are successfully treated. However, a percentage of active TB cases develop further complications. Approximately 7.8% of active TB cases may take a more severe clinical course and lead to death. The TB case fatality rate was estimated using information on reported deaths caused by TB from table 8–5 of the Vital Statistics for the U.S. and cases of TB reported in CDC's TB Surveillance system for 1989 through 1991 (Exs. 7–270, 7–264). As shown in table V–13, the TB case death rate ranged from 69.94 to 89.18 per 1,000 with a 3-year average of 77.85 per 1,000 TB cases. The Agency used the 3-year average (77.85 per 1,000) for its estimate of deaths caused by TB. This estimate is in close agreement with published results from a retrospective cohort study conducted in Los Angeles County on TB cases in 1990 (Ex. 7–268). In this study, all confirmed TB cases reported in the county in 1990 were tracked and the number of deaths where TB was the direct or contributing cause was ascertained. ''Contributing cause'' was defined as a case of TB of such severity that it would have caused the death of the patient had the primary illness not caused death earlier. Of the 1,724 cases included in the study, TB was considered the cause of death or the contributing cause of death in 135 cases (78.31 per 1,000).

TABLE V–13.—TB CASE DEATH RATES FOR ADULTS (18+)

Year	Number of deaths [a]	Number of TB cases [b]	TB case death rate [c]
1991	1,700	24,307	69.94
1990	1,796	23,795	75.48
1989	1,956	21,934	89.18
3-year Average	1,817	23,345	77.85

[a] Source: Vital Statistics for the U.S., Table 8–5, (age 20+).
[b] Source: CDC, TB surveillance system, (age 18+).
[c] Rate expressed per 1,000 TB cases. Any deaths caused by TB in persons 18 or 19 years of age are not included in the numerator.

National estimates of annual and lifetime risk for TB infection, active disease and death caused by TB due to occupational exposure are computed as weighted averages of the state estimates and are presented in table V–14.

TABLE V–14.—AVERAGE OCCUPATIONAL RISK ESTIMATES [a, b] PER 1,000 WORKERS AT RISK

Work setting	Annual TB infection	Lifetime TB infection	Lifetime active TB	Death caused by TB [c]
Hospitals:				
WA	0.68	30	3.0	0.2
NC	5.7	219	22.0	1.7
JM	11.8	386	38.6	3.0
Long-term Care	14.6	448	44.8	3.5
Home Health Care	6.9	225	25.5	2.0
Home Care	1.6	69	6.9	0.5

[a] Weighted by each state's population in 1994.
[b] Risk estimates reflect excess risk due to occupational exposure and are expressed per 1,000 employees at risk.
[c] Number of deaths caused by TB due to occupational exposure are derived based on an estimated TB case death rate of 77.85 per 1,000 cases and are computed by multiplying the lifetime active disease rate by .07785.

(a) *Risk Estimates for Hospital Employees:* Logistic regression analysis of the Washington state hospital data indicated an increase in annual risk (47% above background) for employees with potential exposure to TB. For this particular analysis the control group was defined as those hospitals with no-known TB patients that are located in counties that did not report any active TB cases in 1994. However, an increased risk of 47% above background in the annual infection rate is expected to produce a range of 4 to 72 TB infections per 1000 exposed workers in a working lifetime, which could result in as many as 7 cases of active TB and approximately 1 death per 1,000 exposed workers.

Based on the survey of hospitals in North Carolina's western region, the expected overall risk due to occupational exposure is estimated to be 4 times the background rate. This results in an expected range of lifetime risk between 34 and 472 infections per 1,000 employees at risk for TB infection. Lifetime estimates of active TB cases resulting from these infections are expected to range between 3 and 47, resulting in as many as 4 deaths per 1,000 exposed employees at risk of TB infection. As done previously, the North Carolina study results were adjusted to reflect 1994 TB disease trends.

Based on the data from Jackson Memorial Hospital, the overall risk due to occupational exposure is estimated to be 8 times the background rate. This results in an expected range of lifetime risk between 67 and 723 infections per 1,000 employees at risk. Lifetime estimates of the number of active TB case per 100 exposed workers are expected to range between 7 and 72, resulting in as many as 6 deaths per 1,000 exposed employees at risk for TB infection.

In summary, table V–9 and table V–14 show that the annual occupational risk of infection is expected to range:

(a) From .09 to 1.66 with a weighted average of 0.68 per 1,000 for workplaces located in relatively low TB prevalence areas, and where TB infection measures and engineering controls are required;

(b) From 0.77 to 14.1 with a weighted average of 5.7 per 1,000 for workplaces located in areas with moderate TB prevalence and inadequate TB control programs; and

(c) From 1.54 to 28 with a weighted average of 11.8 per 1,000 for workplaces

located in high TB prevalence areas, serving high risk patients, with high frequency of exposure to infectious TB.

Similarly, the lifetime occupational risk is expected to range:

(a) From 4 to 72 with a weighted average of 30 per 1,000 for workplaces located in relatively low TB prevalence areas, and where TB infection measures and engineering controls are required;

(b) From 34 to 472 with a weighted average of 219 per 1,000 for workplaces located in areas with moderate TB prevalence and inadequate TB control programs; and

(c) From 67 to 723 with a weighted average of 386 per 1,000 for workplaces located in high TB prevalence areas, serving high risk patients, with high frequency of exposure to infectious TB.

Risk estimates derived from either study (Washington State or North Carolina) represent an overall rate of occupational risk, because both studies include PPD skin testing results from the entire hospital employee population, whereas the Jackson Memorial study addresses the occupational risk to workers where exposure to infectious TB is highly probable.

Although the exact compliance rate is not known, hospitals in Washington State have been required to implement the CDC TB guidelines with respect to engineering controls (requiring isolation rooms with negative pressure) and infection control measures (advocating early patient identification, employee training, respiratory protection, and PPD testing).

Neither the facilities in North Carolina nor Jackson Memorial had engineering controls fully implemented at the time these data were collected. Early identification of suspect TB patients has always been recommended in North Carolina. However, engineering controls in isolation rooms were either not present or did not function properly because of modifications in the physical structure of the building (i.e., isolation rooms had been subdivided using partitions, air ducts had been re-directed because of remodeling, etc.). Tuberculin skin testing was very inconsistent and sporadic. In addition, employee training and use of respiratory protection were not emphasized.

By 1991, Jackson Memorial had most of the engineering controls in place in the HIV ward (where the first outbreak took place) and in selected areas with high TB exposure, but not in the entire hospital. However, the staff training program was still being developed and respiratory protection was not always adequate. Although exposures had been greatly reduced, ''high risk'' procedures were still being performed in certain areas of the hospital without adequate engineering controls, such as the Special Immunology clinic where HIV–TB patients received pentamidine treatments. Like the hospitals in the North Carolina study, Jackson Memorial represents a working environment that serves a patient population known to have high TB prevalence. In addition, Jackson Memorial only tested employees with patient contact in areas where active TB had been detected.

(b) *Risk Estimates for Workers in Other Work Settings:* In long-term care facilities for the elderly there is also a significantly increased likelihood that employees will encounter individuals with infectious TB. Persons over the age of 65 constitute a large proportion of the TB cases in the United States. In 1987, CDC reported that persons aged 65 and over accounted for 27% (6150) of the reported cases of active TB in the U.S., although they account for only 12% of the U.S. population. Many of these individuals were infected in the past and advancing age and decreasing immunocompetence have caused them to develop active disease. In 1990 the CDC estimated that approximately 10 million people were infected with TB. As the U.S. population steadily ages, many of these latent infections may progress to active disease. Because elderly persons represent a large proportion of the nation's nursing home residents and because the elderly represent a large proportion of the active cases of TB, there is an increased likelihood that employees at long-term care facilities for the elderly will encounter individuals with infectious TB.

Similarly, there are other occupational settings that serve high-risk client populations and thus have an increased likelihood of encountering individuals with infectious TB. For example, hospices, emergency medical services, and home-health care services provide services to client populations similar to those in hospitals and thus are likely to experience similar risks.

OSHA used information from the 1994 Washington state PPD skin testing survey to estimate occupational risk for workers in long-term care, home health care, and home care. Annual estimates of excess risk for TB infection are presented in TABLE V–10 and lifetime estimates for TB infection, active TB, and death caused by occupational TB are presented in TABLE V–12.

Based on the Washington State data, the overall annual excess risk for TB infection is estimated to be 10-fold over background for workers in long-term care. This results in an expected range of lifetime risk of between 85 and 800 infections per 1,000 employees at risk for TB infection. Lifetime estimates of the number of active TB cases resulting from these infections range from 9 to 81 and are projected to cause as many as 6 deaths per 1,000 exposed employees at risk of TB infection. Similarly, the overall annual excess risk of TB infection for workers in home health care is estimated to be approximately 500% above background. This results in an expected range of lifetime risk of between 41 and 536 infections per 1,000 employees at risk for TB infection. Lifetime estimates of the number of active TB cases range from 4 to 54 per 1,000, and are projected to cause as many as 4 deaths per 1,000 exposed employees at risk of TB infection. Similarly, the overall annual excess risk of TB infection for workers in home care is estimated to be approximately 100% above background. This results in an expected range of lifetime risk of between 10 and 164 infections per 1,000 employees at risk for TB infection. Lifetime estimates of the number of active TB cases range from 1 to 16, and are expected to result in approximately 1 death per 1,000 exposed employees at risk of TB infection.

Clearly, employees in all three groups (long-term care for the elderly, home health care, and home care) have higher risks than hospital employees in Washington. This could be attributed, in part, to the lack of engineering controls in these work settings. That respirators may be used only intermittently may also play a role. Although workers in these three groups are encouraged by local health authorities to use respiratory protection while tending to a suspect TB patient, the actual rate of respirator usage is difficult to ascertain. A third factor that may contribute to higher risk in these work settings is delayed identification of suspect TB patients due to confounding symptoms presented by the individuals. For example, many long-term care residents exhibit symptoms of persistent coughing from decades of smoking. Consequently, an individual in long-term care with a persistent cough may be infectious for several days before he or she is identified as having suspected infectious TB.

Qualitative Assessment of Risk for Other Occupational Settings

The quantitative estimates of the risk of TB infection discussed above are based primarily upon data from hospitals and selected other health care settings. Data from hospitals and certain health care settings were selected because OSHA believes that these data

represent the best information available to the Agency for purposes of quantifying the occupational risks of TB infection and disease. However, as discussed above, it is their exposure to aerosolized *M. tuberculosis* that places these workers at risk of infection and not factors unique to these particular kinds of health care activities. Thus, OSHA believes that the risk estimates derived from hospitals and selected other work settings can be used to describe the potential range of risks for other health care and other occupational settings in which workers can reasonably anticipate frequent and substantial exposure to aerosolized *M. tuberculosis.*

In order to extrapolate the quantitative risk estimates calculated for hospital employees and other selected health care settings, OSHA, as a first step, identified risk factors that place employees at risk of exposure. Some amount of exposure to TB could occur in any workplace in the United States. TB is an infectious disease that occurs in the community and thus, individuals may bring the disease into their own workplace or to other businesses or work settings that they may visit. However, there are particular kinds of work settings where risk factors are present that substantially increase the likelihood that employees will be frequently exposed to aerosolized *M. tuberculosis.* First among these factors is the increased likelihood of exposure to individuals with active, infectious TB. Individuals who are infected with TB have a higher risk of developing active TB if they are (1) immunocompromised (e.g., elderly, undergoing chemotherapy, HIV positive), (2) intravenous drug users, or (3) medically underserved and of generally poor health status (Exs. 6–93 and 7–50). Thus, in work settings in which the client population is composed of a high proportion of individuals who are infected with TB, are immunocompromised, are intravenous drug users or are of poor general health status, there is a greatly increased likelihood that employees will routinely encounter individuals with infectious TB and be exposed to aerosolized *M. tuberculosis.* A second factor that places employees at high risk of exposure to aerosolized *M. tuberculosis* is the performance of high-hazard procedures, i.e., procedures performed on individuals with suspected or confirmed infectious TB where there is a high likelihood of the generation of droplet nuclei. A third factor that places employees at risk of exposure is the environmental conditions at the work setting. Work settings that have overcrowded conditions or poor ventilation will facilitate the transmission of TB. Thus, given that a case of infectious TB does occur, the conditions at the work setting itself may promote the transmission of disease to employees who share airspace with the individual(s) with infectious TB.

The second step in extrapolating the quantitative risks is to identify the types of work settings which have some or all of the risk factors outlined above. Once these work settings have been identified, OSHA believes that it is reasonable to assume that the quantitative risk estimates calculated for hospitals and other selected health care settings can be used to describe the risks in the identified work settings.

Correctional Facilities

Employees in correctional facilities or other facilities that house inmates or detainees have an increased likelihood of frequent exposure to individuals with infectious TB. Many correctional facilities have a higher incidence of TB cases in comparison to the incidence in the general population. In 1985, the CDC estimated that the incidence of TB among inmates of correctional facilities was more than three times higher than that for nonincarcerated adults aged 15–64 (Ex. 3–33). In particular, in states such as New Jersey, New York, and California, the increased incidence of annual TB cases in correctional facilities ranged from 6 to 11 times greater than that of the general population for their respective states (Exs. 7–80 and 3–33). A major factor in the increased incidence of TB cases in correctional facilities is the fact that the population of correctional facilities is over-represented by individuals who are at greater risk of developing active disease, e.g., persons from poor and minority groups who may suffer from poor nutritional status and poor health care, intravenous drug users, and persons infected with HIV. Similarly, certain types of correctional facilities, such as holding facilities associated with the Immigration and Naturalization Service, may have inmates/detainees from countries with a high incidence of TB. For foreign-born persons arriving in the U.S., the case rate of TB in 1989 was estimated to be 124 per 100,000, compared to an overall TB case rate of 9.5 per 100,000 for the U.S. (Ex. 6–26). Moreover, in the period from 1986 to 1989, 22% of all reported cases of TB disease occurred in the foreign-born population. Given the increased prevalence of individuals at risk for developing active TB, there is an increased likelihood that employees working in these facilities will encounter individuals with infectious TB. In addition, environmental factors such as overcrowding and poor ventilation facilitate the transmission of TB. Thus, given that a case of infectious TB does occur, the conditions in the facility itself promote the transmission of the disease to other inmates and employees in the facility who share airspace.

As discussed in the Health Effects section, a number of outbreak investigations (Exs. 6–5, 6–6) have shown that where there has been exposure to aerosolized *M. tuberculosis* in correctional facilities, the failure to promptly identify individuals with infectious TB and provide appropriate infection control measures has resulted in employees being infected with TB. These studies demonstrate that, as in hospitals or health care settings, where there is exposure to aerosolized TB bacilli and where effective control measures are not implemented, exposed employees are at risk of infection. Thus, estimates based on the risk observed among employees in hospitals and in selected other work settings that involve an increased likelihood of exposure can be appropriately applied to employees in correctional facilities.

Recently, scientists at NIOSH have completed a prospective study of the incidence of TB infection among New York State correctional facilities employees (Ex. 7–288). This study is the first prospective study of TB infection among employees in correctional facilities in an entire state. Other studies have reported on contact investigations, which seek to identify recent close contacts with an index case and determine who might subsequently have been infected. Studies based on contact investigations have the advantage of a good definition of potential for exposure and they serve to identify infected persons for public health purposes. On the other hand, prospective studies of an entire working group have the advantage of covering the entire population potentially at risk, of considering all inmate cases simultaneously as potential sources of infection, and, most importantly, of permitting the calculation of incidence rates and risk attributable to occupational exposure.

Following an outbreak of active TB among inmates that resulted in transmission to employees in 1991, the state of New York instituted a mandatory annual tuberculin skin testing program to detect TB infection among employees. The authors used data from the first two years of testing to estimate the incidence of TB infection

among 24,487 employees of the NY Department of Corrections. Subjects included in the study had to have two sequential PPD skin tests, have a negative test the first year, and have complete demographic information. The overall conversion rate was estimated to be 1.9%. Preliminary results show that after controlling for age, ethnicity, gender, and residence in New York City, corrections offices and medical personnel, working in prisons with inmate active TB cases, had odds ratios of TB infection of 1.64 and 2.39, respectively, compared to maintenance and clerical personnel who had little opportunity for prisoner contact. Based on these results, the annual excess risk due to occupational exposure is estimated to be 1.22% and 2.64% for corrections officers and medical personnel, respectively. This translates into lifetime occupational risks of 423 and 700 per 1,000 exposed employees, respectively. In prisons with no known inmate TB cases, there were no significant differences in TB infection rates among employees in different job categories.

Homeless Shelters

Employees in homeless shelters also have a significantly increased likelihood of frequent exposure. A high prevalence of TB infection and disease is common in many homeless shelters. Screening in selected shelters has shown the prevalence of TB infection to range from 18 to 51% (Ex. 6–15). Many shelter residents also possess characteristics that impair their immunity and thus place them at greater risk of developing active disease. For example, homeless persons often suffer from poor nutrition and poor overall health status, and they also have poor access to health care. In addition, they may suffer from alcoholism, drug abuse and infection with HIV. Screening of selected shelters has shown the prevalence of active TB disease to range from 1.6 to 6.8% (Ex. 6–15). Thus, there is an increased likelihood that employees at homeless shelters will frequently encounter individuals with infectious TB in the course of their work.

In addition, as in the case for correctional facilities, homeless shelters also tend to be overcrowded and have poor ventilation, factors that promote the transmission of disease and place shelter residents and employees at risk of infection. Outbreaks reported among homeless shelters (Exs. 7–51, 7–75, 7–73, 6–25) also provide evidence that where there is exposure to individuals with infectious TB and effective infection control measures are not implemented, employees are at risk of infection. It is reasonable to assume, therefore, that risk estimates calculated for hospital employees who have an increased likelihood of exposure to individuals with infectious TB can be used to estimate the risks for homeless shelter employees.

Facilities That Provide Treatment for Drug Abuse

Employees in facilities that provide treatment for drug abuse have an increased likelihood of frequent exposure to individuals with infectious TB. Surveys of selected U.S. cities by the CDC have shown the prevalence of TB infection among the clients of drug treatment centers to range from approximately 10% to 13% (Ex. 6–8). Clients of these centers are also generally at higher risk of developing active disease. The clients typically come from medically underserved populations and may suffer from poor overall health status. As discussed in the Health Effects section, drug dependence has also been shown to be a possible risk factor in the development of active TB. Moreover, many of the drug treatment center clients are intravenous drug users and are infected with HIV, placing these individuals at an increased risk of developing active TB. Given these risk factors for the clients served at drug treatment centers, there is an increased likelihood that employees in these work settings will be exposed frequently to individuals with infectious TB.

Medical Laboratories

Medical laboratory work is a recognized source of occupational hazards. CDC considers workers in medical laboratories that handle *M. tuberculosis* to be at high risk for occupational transmission of TB either because of the volume of material handled by routine diagnostic laboratories or the high concentrations of pathogenic agents often handled in research laboratories.

Few surveys of laboratory-acquired infections have been undertaken; most reports are of small outbreaks in specific laboratories. Sulkin and Pike's study of 5,000 laboratories suggested that brucellosis, tuberculosis, hepatitis, and enteric diseases are among the most common laboratory-acquired infections (Ex. 7–289). In 1957, Reid noted that British medical laboratory workers had a risk of acquiring tuberculosis two to nine times that of the general population (Ex. 7–289). This result was validated in 1971 by Harrington and Channon in their study of medical laboratories (Ex. 7–289). A retrospective postal survey of approximately 21,000 medical laboratory workers in England and Wales showed a five-times increased risk of developing active TB among these workers as compared with the general population. Technicians were at greater risk, especially if they worked in anatomy departments. A similar survey carried out in 1973 of 3,000 Scottish medical laboratory workers corroborates the results from England and Wales. Three cases, one doctor and two technicians, were noted in the 1973 survey, which resulted in an overall incidence rate of 109 per 100,000 person-years. The general population incidence rate for active TB was 26 per 100,000 person-years, giving a risk ratio of 4.2 (Ex. 7–289).

The studies reviewed in this section indicate that workers in medical laboratories with potential for exposure to *M. tuberculosis* during the course of their work have a several-fold (ranging from 2- to 9-fold) increased risk of developing active disease compared with the risk to the general population. Although these studies were conducted over two decades ago, they represent the most recent data available to the Agency, and OSHA has no reason to believe that the conditions giving rise to the risk of infection at that time have changed substantially in the interim. The Agency is not aware of any more current data on transmission rates in medical laboratories. OSHA solicits information on additional studies addressing occupational exposure to active TB in laboratories; such studies would then be considered by OSHA in the development of a final rule.

Other Work Settings and Activities

In addition to the information available for correctional facilities, homeless shelters, and facilities that provide treatment for drug abuse, there are other work settings and activities where there is an increased likelihood of frequent exposure to aerosolized *M. tuberculosis.* For example, hospices serve client populations similar to those of hospitals and perform similar services for these individuals. Individuals who receive care in hospices are likely to suffer from medical conditions (e.g., HIV disease, end-stage renal disease, certain cancers) that increase their likelihood of developing active TB disease once infected. Thus, employees providing hospice care have an increased likelihood of being exposed to aerosolized *M. tuberculosis*. CDC has recommended that hospices follow the same guidelines for controlling TB that hospitals follow.

Emergency medical service employees also have an increased likelihood of

encountering individuals with infectious TB. Like hospices, emergency medical services cater to the same high risk client populations as hospitals. Moreover, emergency medical services are often used to transport individuals identified with suspected or confirmed infectious TB from various types of health care settings to facilities with isolation capabilities.

In addition, other types of services (e.g., social services, legal counsel, education) are provided to individuals who have been identified as having suspected or confirmed infectious TB and have been placed in isolation or confined to their homes. Employees who provide social welfare services, teaching, law enforcement or legal services to those individuals who are in AFB isolation are exposed to aerosolized *M. tuberculosis*. In particular, employees performing high-hazard procedures are likely to generate aerosolized *M. tuberculosis* by virtue of the procedure itself. Thus, employees providing these types of services also have an increased likelihood of exposure to aerosolized *M. tuberculosis* and are therefore likely to experience risks similar to those described above for hospital workers.

Although they do not have contact with individuals with infectious TB, employees who repair and maintain ventilation systems which carry air contaminated with *M. tuberculosis* and employees in laboratories who manipulate tissue samples or cultures contaminated with *M. tuberculosis* also have an increased likelihood of being exposed to aerosolized *M. tuberculosis*. Like employees in the work settings discussed above, these employees have an increased risk of frequent exposure to aerosolized *M. tuberculosis*.

Therefore, OSHA believes that the quantitative risk estimates derived from data observed among health care workers in the hospital setting can be generally used to describe the potential range of risks for workers in other occupational settings where there is a reasonable anticipation of exposure to aerosolized *M. tuberculosis*. The reasonableness of this assumption is supported by the overall weight of evidence of the available health data. As discussed in the Health Effects section, epidemiological studies, case reports and outbreak investigations have shown that in correctional facilities, homeless shelters, long-term care facilities for the elderly, drug treatment centers, and laboratories where appropriate TB infection control programs have not been implemented, employees have become infected with TB as a result of occupational exposure to individuals with infectious TB or to other sources of aerosolized *M. tuberculosis*. Thus, although the data on employee conversion rates in other work settings cannot be used to directly quantify the occupational risk of infection for those work settings, there is strong evidence that employees in various work settings other than hospitals can reasonably be anticipated to have exposure to aerosolized *M. tuberculosis* and that TB can be transmitted in these workplaces when appropriate TB infection control programs are not implemented.

VI. Significance of Risk

Section 6(b)(5) of the OSH Act vests authority in the Secretary of Labor to issue health standards. This section provides, in part, that:

> The Secretary, in promulgating standards dealing with toxic materials or harmful physical agents under this subsection, shall set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life.

OSHA's overall analytical approach to making a determination that workplace exposure to certain hazardous conditions presents a significant risk of material impairment of health is a four step process consistent with interpretations of the OSH Act and rational, objective policy formulation. In the first step, a quantitative risk assessment is performed where possible and considered with other relevant information to determine whether the substance to be regulated poses a significant risk to workers. In the second step, OSHA considers which, if any, of the regulatory alternatives being considered will substantially reduce the risk. In the third step, OSHA examines the body of ''best available evidence'' on the effects of the substance to be regulated to set the most protective requirements that are both technologically and economically feasible. In the fourth and final step, OSHA considers the most cost-effective way to achieve the objective.

In the Benzene decision, the Supreme Court indicated when a reasonable person might consider the risk significant and take steps to decrease it. The Court stated:

> It is the Agency's responsibility to determine in the first instance what it considers to be ''significant'' risk. Some risks are plainly acceptable and others are plainly unacceptable. If, for example, the odds are one in a billion that a person will die from cancer by taking a drink of chlorinated water, the risk could not be considered significant. On the other hand, if the odds are one in a thousand that regular inhalation of gasoline vapors that are 2% benzene will be fatal, a reasonable person might well consider the risk significant and take the appropriate steps to decrease or eliminate it. (*I.U.D.* v. *A.P.I.*), 448 U.S. at 655).

The Court indicated that ''while the Agency must support its findings that a certain level of risk exists with substantial evidence, we recognize that its determination that a particular level of risk is 'significant' will be based largely on policy considerations.'' The Court added that the significant risk determination required by the OSH Act is ''not a mathematical straitjacket'' and that ''OSHA is not required to support its findings with anything approaching scientific certainty.'' The Court ruled that ''a reviewing court (is) to give OSHA some leeway where its findings must be made on the frontiers of scientific knowledge and that the Agency is free to use conservative assumptions in interpreting the data with respect to carcinogens, risking error on the side of overprotection rather than underprotection.'' (448 U.S. at 655, 656).

As a part of the overall significant risk determination, OSHA considers a number of factors. These include the type of risk presented, the quality of the underlying data, the reasonableness of the risk assessments, and the statistical significance of the findings.

The hazards presented by the transmission of tuberculosis, such as infection, active disease, and death are very serious, as detailed above in the section on health effects. If untreated, 40–60% of TB cases have been estimated to result in death (Exs. 5–80, 7–50, 7–66). Fortunately, TB is a treatable disease. The introduction of antibiotic drugs for TB has helped to reduce the mortality rate by 94% since 1953 (Ex. 5–80). However, TB is still a fatal disease in some cases. From 1989–1991 CDC reported 5,452 deaths among adults from TB (see TABLE V–13, Risk Assessment section). In addition, there has been an increase in certain forms of drug-resistant TB, such as MDR–TB, in which the tuberculosis bacilli are resistant to one or more of the front line drugs such as isoniazid and rifampin, two of the most effective anti-TB drugs. The information available today is not adequate to estimate the future course of MDR–TB, but the reduction in the potential of transmitting this deadly form of the disease is itself another benefit of this standard. The current data indicate that among MDR–TB cases, the risk of death is increased compared to drug-susceptible forms of the disease. A CDC investigation of 8

outbreaks of MDR–TB revealed that among 253 people infected with MDR–TB, 75% died within a period 4 to 16 weeks after the time of diagnosis (Ex. 38–A). MDR–TB may be treated, but due to the difficulty in finding adequate therapy which will control the bacilli's growth, individuals with this form of the disease may remain infectious for longer periods of time, requiring longer periods of hospitalization, additional lost worktime, and an increased likelihood of spreading TB infection to others until treatment renders the patient non-infectious. Because of the difficulty in controlling these drug-resistant forms of the disease with antibiotics, progressive lung destruction may progress to the point where it is necessary to remove portions of the lung to treat the advance of the disease.

The OSH Act directs the Agency to set standards that will adequately assure, to the extent feasible, that no employee will suffer ''material impairment of health or functional capacity.'' TB infection represents a material impairment of health that may lead to active disease, tissue and organ damage, and death. Although infected individuals may not present any signs or symptoms of active disease, being infected with TB bacilli is a serious threat to the health status of the infected individual. Individuals who are infected have a 10% chance of developing active disease at some point in their life, a risk they would not have had without being infected. The risk of developing active disease is even greater for individuals who are immunocompromised, due to any of a large number of factors. For example, individuals infected with HIV have been estimated as having an 8–10% risk *per year* of developing active disease (Ex. 4B).

In addition, since infected individuals commonly undergo treatment with anti-TB drugs to prevent the onset of active disease, they face the additional risk of serious side effects associated with the highly toxic drugs used to treat TB. Preventive treatment with isoniazid, one of the drugs commonly used to treat TB infection, has been shown in some cases to result in death from hepatitis or has damaged the infected person's liver to the extent that liver transplantation was performed (Ex. 6–10). Thus, the health hazards associated with TB infection clearly constitute material impairment of health.

Clinical illness, i.e., active disease, also clearly constitutes material impairment of health. Left untreated, 40 to 60 percent of active cases may lead to death (Exs. 7–50, 7–66, 7–80). Individuals with active disease may be infectious for various periods of time and often must be hospitalized. Active disease is marked by a chronic and progressive destruction of the tissues and organs infected with the bacteria. Active TB disease is usually found in the lungs (i.e., pulmonary tuberculosis). Long-term damage can result even when cases of TB are cured; a common result of TB is reduced lung function (impaired breathing) due to lung damage (Ex. 7–50, pp. 30–31). Inflammatory responses caused by the disease produce weakness, fever, chest pain, cough, and, when blood vessels are eroded, bloody sputum. Also, many individuals have drenching night sweats over the upper part of the body several times a week. The intensity of the disease varies, ranging from minimal symptoms of disease to massive involvement of many tissues, with extensive cavitation and debilitating constitutional and respiratory problems. Long-term damage can also result from extrapulmonary forms of active disease; such damage may include mental impairment from meningitis (infection of membranes surrounding the brain and spinal cord) and spinal deformity and leg weakness due to infection of the vertebrae (i.e., skeletal TB) (Ex. 7–50, p. 31). Active disease is treatable but it must be treated with potent drugs that have to be taken for long periods of time. The drugs currently used to treat active TB disease may be toxic to other parts of the body. Commonly reported side effects of anti-TB drugs include hepatitis, peripheral neuropathy, optic neuritis, ototoxicity and renal toxicity (Ex. 7–93). Active disease resulting from infection with MDR–TB is of even greater concern due to the inability to find adequate drug regimens. Although OSHA has not been able to precisely quantify the increase in incidence of MDR–TB, the number of cases of MDR–TB is clearly on the rise. In these cases, individuals may remain infectious for longer periods of time and may suffer more long-term damage from the chronic progression of the disease until adequate therapy can be identified.

In this standard, OSHA has presented quantitative estimates of the lifetime risk of TB infection, active disease and death from occupational exposure to *M. tuberculosis*. Qualitative evidence of occupational transmission is also included in OSHA's risk assessment.

In preparing its quantitative risk assessment, OSHA began by seeking out occupational data associated with TB infection incidence in order to calculate an estimate of risk for TB infection attributable to occupational exposure for all U.S. workers. Unfortunately, an overall national estimate of risk for TB infection attributable to occupational exposure is not available. CDC, which collects and publishes the number of active TB cases reported nationwide each year, does not publish occupational data associated with the incidence of TB infection and active TB on a nationwide basis. There has been some effort to include occupational information on the TB reporting forms, but only a limited number of states are currently using the new forms and capturing occupational information in a systematic way. In the absence of a national database, OSHA used two statewide studies, from North Carolina and Washington (Exs. 7–7, 7–263), and data from an individual hospital, Jackson Memorial Hospital (Ex. 7–108), on conversion rates of TB infection for workers in hospitals. The Washington State database also contained information on three additional occupational groups: long-term care, home health care and home care employees. OSHA used these data to model average TB infection rates and estimate the range of expected risks in the U.S. among workers with occupational exposure to TB.

The conversion rates in the selected studies were used to estimate the annual excess relative risk due to occupational exposure, which was expressed as the percent increase of infection above each study's control group. In order to estimate an overall range of occupational risk of TB infection, taking into account regional differences in TB prevalence in the U.S. and indirectly adjusting for factors such as socio-economic status, which might influence the rate of TB observed in different parts of the country, OSHA: (1) Estimated background rates of infection for each state by assuming that the number of new infections is functionally related to the number of active cases reported by the state each year (i.e., the distribution of new infections is directly proportional to the distribution of active cases), and 2) applied estimates of the annual excess relative risk, derived from the occupational studies, to the state background rates to calculate estimates of excess risk due to occupational exposure by state. Thus, the excess occupational risk estimates are actually calculated from the three available studies, on a relative increase basis, and these relative increases are multiplied by background rates for each state to derive estimates of excess occupational risk by state. The state estimates are then used to derive a national estimate of annual occupational risk of TB infection. Given an annual rate of infection, the lifetime risk of infection was calculated assuming that workers

are exposed for 45 years and that the worker's exposure profile and working conditions remain constant throughout his or her working lifetime. Lifetime infection rates are then used to calculate the lifetime risk of developing active disease based on the estimate that 10% of all infections result in active disease. Given a number of active cases of TB, the number of expected deaths can be calculated based on the estimated average TB case death rate (i.e., number of TB deaths per number of active TB cases averaged over 3 years as reported by CDC).

OSHA estimates that the risk of material impairment of health or functional capacity, that is, the average lifetime occupational risk of TB infection for hospital workers ranges from 30 to 386 infections per 1,000 workers who are occupationally exposed to TB. These are different national averages, each derived by calculating the risk in each state and weighting it by the state's population. The low end of this range is derived by using the Washington State data, and is likely to seriously underestimate the true risk to which workers are exposed. This is because the Washington data represent occupational exposures among employees in hospitals which are located in areas of the country with a low prevalence of active TB and which have implemented TB controls (e.g., early identification procedures, annual skin testing, and negative pressure in AFB isolation rooms). The high end of this range is derived by using the Jackson Memorial Hospital study, and represents occupational risk for workers in hospitals located in high TB prevalence areas, serving high risk patients, and with a high frequency of exposure to infectious TB.

OSHA also used information from the Washington State database to estimate national average estimates of lifetime risk for workers in long-term care (i.e., nursing homes), home health care, and home care. The national average lifetime risk of TB infection is estimated to be 448 per 1,000 for workers in long-term care facilities, 225 per 1,000 for workers in home health care (primarily nursing staff), and 69 per 1,000 for workers in home care. The higher likelihood of occupational exposure in long-term care facilities (early identification of suspect TB cases is often difficult among the elderly) and the presence of fewer engineering controls in these facilities may explain the high observed occupational risk in that work setting.

The national average lifetime risk of developing active disease ranges from approximately 3 to 39 cases per 1,000 exposed employees for workers in hospital settings. Similarly, the average lifetime risk of active disease is estimated to be approximately 45 per 1,000 for workers in long-term care, 26 per 1,000 in home health care, and 7 per 1,000 in home care. This range is based on the estimate that 10% of infections will progress to active disease over one's lifetime. This risk may be greater for immunocompromised individuals.

The national average lifetime risk of death from TB ranges from 0.2 to approximately 3 deaths per 1,000 exposed employees for workers in hospital settings. Similarly, the average lifetime risk of death from TB is estimated to be approximately 3.5 per 1,000 for workers in long-term care, 2 per 1,000 for workers in home health care, and 0.5 per 1,000 in home care. The lower range of the national lifetime risk of deaths, 0.2 per 1,000, is based on the Washington State hospital data where the prevalence of TB is low and infection control measures have been implemented. Thus, this lower range of risk underestimates the risk of death from TB for other employees who work in settings where infection control measures, such as those outlined in this proposed standard, have not been implemented. The risk assessment data show that where infection control measures were not in place, the estimated risk of death from TB was as high as 6 deaths per 1,000 exposed employees.

The quantitative risk estimates are based primarily upon data from hospitals and selected other work settings. However, it is frequent exposure to aerosolized *M. tuberculosis* which places workers at substantially increased risk of infection and not factors unique to the health care profession or any job category therein. Qualitative evidence, such as that from the epidemiological studies, case reports and outbreak investigations reported for various types of work settings, as discussed earlier in the Health Effects section, clearly demonstrates that employees exposed to aerosolized *M. tuberculosis* have become infected with TB and have gone on to develop active disease. These work settings share risk factors that place employees at risk of transmission. For example, these work settings serve client populations that are composed of a high prevalence of individuals who are infected with TB, are immunocompromised, are injecting drug users or are medically underserved and of poor general health status. Therefore, there is an increased likelihood that employees in these work settings will encounter individuals with active TB. In addition, high-hazard procedures, such as bronchoscopies, are performed in some of these work settings, which greatly increases the likelihood of generating aerosolized *M. tuberculosis.* Moreover, some of the work settings have environmental conditions such as overcrowding and poor ventilation, factors that facilitate the transmission of disease. Therefore, OSHA believes that the quantitative risk estimates based on hospital data and other selected health care settings can be extrapolated to other occupational settings where there is a similar increased likelihood of exposure to aerosolized *M. tuberculosis.*

Having specific data for non-health care workers and workplace conditions would add more precision to the quantitative risk assessment, but that level of detail is not possible with the currently available information. However, the Agency believes that such a level of detail is not necessary to make its findings of significant risk because the risk of infection is based upon occupational exposure to aerosolized *M. tuberculosis.* Nevertheless, OSHA seeks information on conversion rates and the incidence of active disease among employees in non-health care work settings in order to give more precision to its estimates of risk.

OSHA's risk estimates for TB infection are comparable to other risks which OSHA has concluded are significant, and are substantially higher than the example presented by the Supreme Court in the Benzene Decision. After considering the magnitude of the risk as shown by the quantitative and qualitative data, OSHA preliminarily concludes that the risk of material impairment of health from TB infection is significant.

OSHA also preliminarily concludes that the proposed standard for occupational exposure to TB will result in a substantial reduction in that significant risk. The risk of infection is most efficiently reduced by implementing TB exposure control programs for the early identification and isolation of individuals with suspected or confirmed infectious TB. Engineering controls to maintain negative pressure in isolation rooms or areas where infectious individuals are being isolated will reduce the airborne spread of aerosolized *M. tuberculosis* and subsequent exposure of individuals, substantially reducing the risk of infection. In addition, for those employees who must enter isolation rooms or provide services to individuals with infectious TB, respiratory protection will reduce exposure to aerosolized *M. tuberculosis* and thus reduce the risk of infection.

Several studies have shown that the implementation of infection control measures such as those outlined in this proposed standard have resulted in a reduction in the number of skin test conversions among employees with occupational exposure to TB. For example, results of a survey conducted by the Society of Healthcare Epidemiology of America (SHEA) of its member hospitals (Exs. 7–147 and 7–148) revealed that among hospitals that treated 6 or more patients with infectious TB per year there were 68% fewer tuberculin skin test conversions in hospitals that had AFB isolation rooms with one patient per room, negative pressure, exhaust air directed outside and six or more air changes per hour, compared to hospitals that did not have AFB isolation rooms with these same characteristics. Similarly, an 88% reduction in tuberculin skin test conversions was observed in an Atlanta hospital after the implementation of infection control measures such as an expanded respiratory isolation policy, improved diagnostic and testing procedures, the hiring of an infection control coordinator, expanded education of health care workers, increased frequency of tuberculin skin tests, implementation of negative pressure, and use of submicron masks for health care workers entering isolation rooms (Ex. 7–173). Improvements in infection control measures in a Florida hospital after an outbreak of MDR-TB reduced tuberculin skin test conversions from 28% to 18% to 0% over three years (Ex. 7–167). These improvements included improved early identification procedures, restriction of high-hazard procedures to AFB isolation rooms, increased skin testing, expansion of initial TB treatment regimens, and daily inspection of negative pressure in AFB isolation rooms. Thus, these investigations show that the implementation of infection control measures such as those included under OSHA's proposed standard for TB can result in substantial reductions in infections among exposed employees.

As discussed in further detail in the following section of the Preamble to this proposed standard, OSHA estimates that full implementation of the proposed standard for TB will result in avoiding approximately 21,400 to 25,800 work-related infections per year, 1,500 to 1,700 active cases of TB resulting from these infections and 115 to 136 deaths resulting from these active cases. In addition, because the proposed standard encourages the identification and isolation of active TB cases in the client populations served by workers in the affected industries, there will also be non-occupational TB infections that will be averted. OSHA estimates that implementation of the proposed standard will result in avoiding approximately 3,000 to 7,000 non-occupational TB infections, 300 to 700 active cases of TB resulting from these infections, and 23 to 54 deaths resulting from these active cases. OSHA preliminarily concludes that the proposed standard for TB will significantly reduce the risk of infection, active disease and death from exposure to TB and that the Agency is thus carrying out the Congressional intent and is not attempting to reduce insignificant risks.

Although the current OSHA enforcement program, which is based on the General Duty Clause of the Act, Section 5(a)(1), and the application of some general industry standards, such as 29 CFR 1910.134, Respiratory Protection, has reduced the risks of occupational exposure to tuberculosis to some extent, significant risks remain and it is the Agency's opinion that an occupational health standard promulgated under section 6(b) of the Act will much more effectively reduce these risks for the following reasons. First, because of the standard's specificity, employers and employees are given more guidance in reducing exposure to tuberculosis. Second, it is well known that a standard is more protective of employee health than an enforcement program based upon the general duty clause and general standards. Unlike the proposed standard, the general duty clause specifies no abatement methods and the general industry standards do not set forth abatement methods specifically addressing occupational exposure to TB. Third, the general duty clause imposes heavy litigation burdens on OSHA because the Agency must prove that a hazard exists at a particular workplace and that it is recognized by the industry or the cited employer. Since the proposed standard specifies both the conditions that trigger the application of the standard and the employer's abatement obligations, thereby establishing the existence of the hazard, no independent proof that the hazard exists in the particular workplace need be presented. The reduction in litigation burdens will mean that the Labor Department, as well as the employer, will save time and money in the investigation and litigation of occupational TB cases. Finally, the promulgation of this proposed standard will result in increased protection for employees in state-plan states which, although not required to adopt general duty clauses, must adopt standards at least as effective as Federal OSHA standard.

In summary, the institution of the enforcement guidelines has been fruitful, but it has not eliminated significant risks among occupationally exposed employees. Therefore, OSHA preliminarily concludes that a standard specifically addressing the risks of tuberculosis is necessary to further substantially reduce significant risk. OSHA's preliminary economic analysis and regulatory flexibility analysis indicate that the proposed standard is both technologically and economically feasible. OSHA's analysis of the technological and economic feasibility is discussed in the following section of the preamble.

VII. Summary of the Preliminary Economic Analysis and Regulatory Flexibility Analysis

OSHA is required by the Occupational Safety and Health Act of 1970 and several court cases pertaining to that Act to ensure that its rules are technologically and economically feasible for firms in the affected industries. Executive Order (EO) 12866 and the Regulatory Flexibility Act (as amended) also require Federal agencies to estimate the costs, assess the benefits, and analyze the impacts on the regulated community of the regulations they propose. The EO additionally requires agencies to explain the need for the rule and examine regulatory and non-regulatory alternatives that might achieve the objectives of the rule. The Regulatory Flexibility Act requires agencies to determine whether the proposed rule will have a significant economic impact on a substantial number of small entities, including small businesses and small government entities and jurisdictions. For proposed rules with such impacts, the agency must prepare an Initial Regulatory Flexibility Analysis that identifies those impacts and evaluates alternatives that will minimize such impacts on small entities. OSHA finds that the proposed rule is ''significant'' under Executive Order 12866 and ''major'' under Section 804(2) of the Small Business Regulatory Enforcement Fairness Act of 1996. Accordingly, the Occupational Safety and Health Administration (OSHA) has prepared this Preliminary Economic and Regulatory Flexibility Analysis (PERFA) to support the Agency's proposed standard for occupational exposure to tuberculosis (TB). The following is an executive summary of that analysis. The entire test of the PERFA can be found in the rulemaking docket as Exhibit 13.

The complete PERFA is composed of various chapters that describe in detail the information summarized in the following section.

Statement of Need

TB is a communicable, potentially lethal disease caused by the inhalation of droplet nuclei containing the bacillus *Mycobacterium tuberculosis* (*M. tuberculosis*). Persons exposed to these bacteria can respond in different ways: by overcoming the challenge without developing TB, by becoming infected with TB, or by developing active TB disease. Those who become infected harbor the infection for life, and have a 10 percent chance of having their infection progress to active disease at some point in their life. Those with active disease have the signs and symptoms of TB (e.g., prolonged, productive cough; fatigue; night sweats; weight loss) and have about an 8 percent risk of dying from their disease.

TB has been a worldwide health problem for centuries, causing millions of deaths worldwide. In the United States, however, there has been a decline in the number of active TB cases over the last four decades. Between 1953 and 1994, the number of active cases declined from 83,304 to 24,361, an annual rate of decline of 3.6 percent over the period as a whole (Figure VII–1). The 1988–1992 period, however, saw the first substantial increase in the number of active cases since 1953. A number of outbreaks of this disease have occurred among workers in health care settings, as well as other work settings, in recent years. To add to the seriousness of the problem, some of these outbreaks have involved the transmission of multi-drug resistant strains of *M. tuberculosis,* which are often fatal. Very recently, i.e., after 1992, this trend has reversed, and the number of such cases appears once again to have begun to decline. Nevertheless, TB remains a major health problem, with 22,813 active cases reported in 1995. Because active TB is endemic in many U.S. populations—including groups in both urban and rural areas—workers who come into contact with diseased individuals are at risk of contracting the disease themselves.

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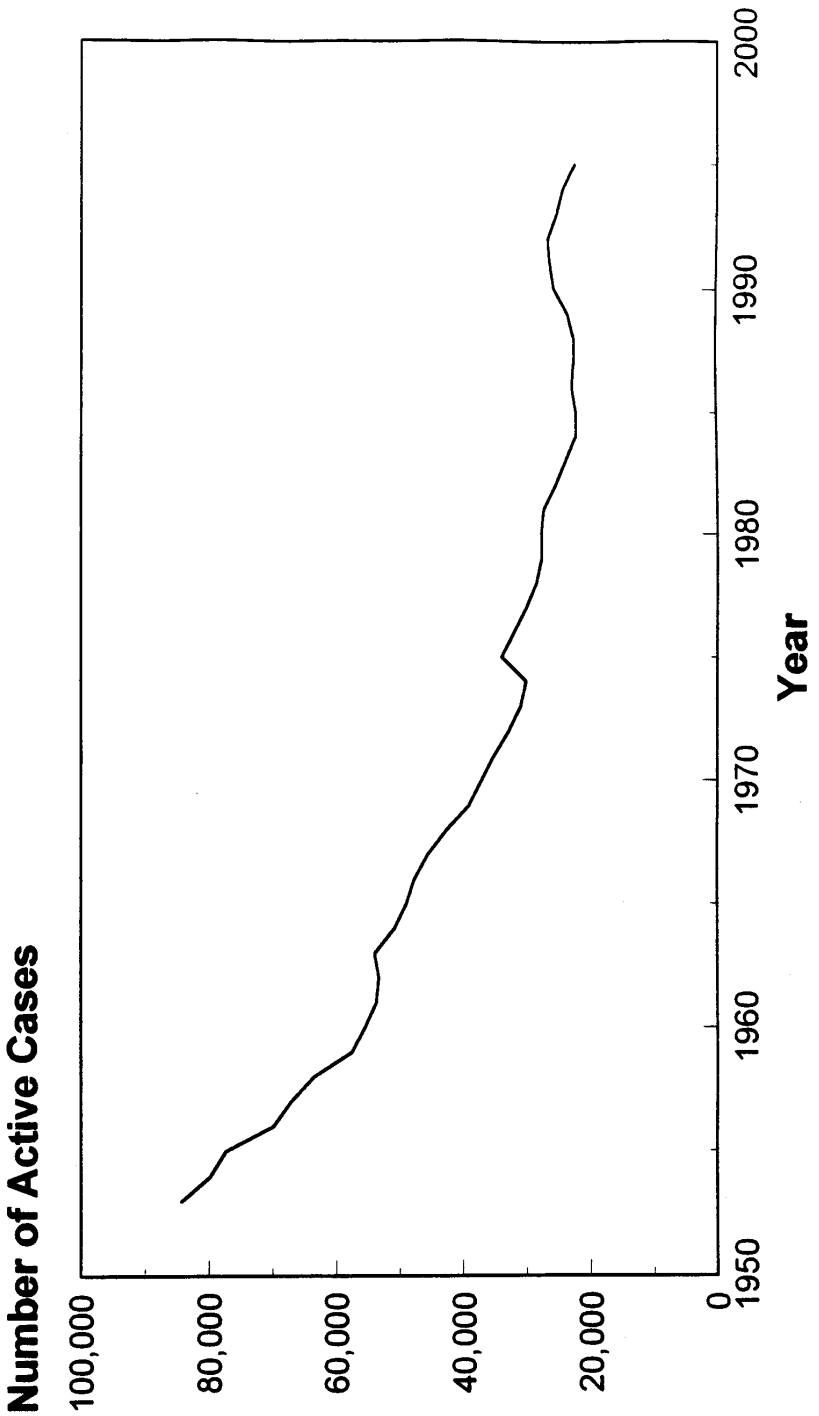
Figure VII-1. Cases of Tuberculosis by Year (1953-1995)



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Many occupational groups, including workers in health care, nursing homes, homeless shelters, hospices, correctional facilities, laboratories, physicians' offices, and other settings are at risk of contracting TB on the job. These workers are at risk because they are exposed in the course of their work to patients and others with active TB disease, perform procedures that expose them to airborne concentrations of *M. tuberculosis,* or serve client populations where the incidence of active disease is unusually high.

The purpose of OSHA's standard is to reduce these risks in health care and other work settings where active TB cases are likely to be encountered by employees. To accomplish this goal, the proposed standard requires those employers who are responsible for the working conditions where such encounters occur to implement a program of infection prevention and infection control that is designed to prevent occupational infections in the first place, and to identify and treat any job-related infections that do occur. The approach taken in the proposed standard is similar to that adopted by OSHA in its 1991 bloodborne pathogens standard, which is given credit for achieving a dramatic reduction in the number of cases of hepatitis among health care and other workers since it was issued. OSHA predicts that, once implemented, the proposed TB standard will have similar results, achieving reductions on the order of 70 to 90 percent in the number of TB infections, active cases, and directly related deaths.

This Preliminary Economic and Regulatory Flexibility Analysis includes an introductory chapter that describes the major provisions of the standard. The proposal would apply to occupational exposure to TB occurring in, during, or through the provision of services by:

- Hospitals.
- Nursing homes.
- Correctional facilities.
- Immigration detainment facilities.
- Law enforcement facilities.
- Hospices.
- Substance abuse treatment centers.
- Homeless shelters.
- Medical examiners' offices.
- Home health care providers.
- Emergency medical services.
- Research and clinical laboratories handling TB.
- Contract work on ventilation systems or areas of buildings that may contain aerosolized *M. tuberculosis.*
- Physicians performing certain high hazard procedures.
- Social service workers providing services to individuals identified as having suspected or confirmed infectious TB.
- Personnel service agencies when providing workers to covered facilities.
- Attorneys visiting known or suspected infectious TB patients.

The groups, industries, and work settings covered by the standard have been included in its scope for specific reasons. For example, hospitals are included because they treat patients with active TB disease, while hospices, certain laboratories, pulmonary and certain other physicians, medical examiners, and contract HVAC workers are covered because employees in these settings/jobs are exposed to aerosolized *M. tuberculosis* during the performance of high-hazard procedures, such as bronchoscopies, sputum induction, autopsies, and during work on ventilation systems that may contain TB bacteria. Other work settings, such as homeless shelters and nursing homes, are covered because their employees serve a client population known to have a high incidence of TB infection. Another group of employees included within the scope of the standard are workers who must occasionally serve patients with active TB who are being treated in ''isolation,'' i.e., a room or area specifically designed to contain the TB microorganism and prevent its spread to surrounding areas. Attorneys and social workers are typical of this group. Finally, the proposed standard covers personnel service agencies that provide temporary, seasonal, or ''leased'' personnel to hospitals and other covered work settings.

OSHA estimates that the standard would apply to approximately 102,000 establishments and provide protection to more than 5 million workers currently at risk of occupational exposure to TB. More than half of these workers—almost 4 million—work in the two industries most affected by the standard: hospitals and nursing homes. Other covered industries with large numbers of workers are home health care, emergency medical services, and correctional institutions.

Table VII–1 shows the number of affected establishments and the population at risk for each covered industry. (Table VII–1 does not include all sectors that might hypothetically be covered by the standard. For example, a chiropractor who engaged in high hazard procedures would be covered by the standard. However, this possibility is sufficiently rare for this activity not to have been included in this analysis. OSHA solicits comments on any affected job categories or industries it may have omitted.) Because the standard requires employers in the covered industries to make an initial determination that will identify which job classifications, employees, and activities within their workplace involve occupational exposure to TB, its requirements are narrowly targeted to those workers most at risk. Thus, for example, only approximately 57 percent of hospital workers are potentially affected by the standard; these workers would include those working on infectious disease floors or wards, radiology units, autopsy suites, and in other, similarly exposed locations.

TABLE VII–1.—NUMBER OF AFFECTED ESTABLISHMENTS AND POPULATION AT RISK, BY INDUSTRY

Industry	Number of affected establishments	Population at risk
Hospitals	5,749	2,663,996
Nursing Homes	20,254	1,200,034
Correctional Institutions	2,079	268,432
Immigration Detainment	12	990
Law Enforcement	4,950	27,469
Hospices	1,755	17,250
Homeless Shelters	10,450	85,168
Substance Abuse Treatment Centers	9,730	120,115
Medical Examiners	100	2,000
Home Health Care	10,921	418,538
Emergency Medical Services	5,099	255,200
Laboratories	851	11,108
Contract HVAC	300	2,500
Social Services	2,342	20,000
Physicians	21,698	43,395
Pulmonary Physicians	1,853	3,705
Personnel Services	1,426	161,608
Attorneys	2,306	4,611
Total	101,875	5,306,119

Source: U.S. Department of Labor, OSHA, Office of Regulatory Analysis.

Technological Feasibility

Chapter III of the analysis evaluates the technological feasibility of the proposed standard for affected establishments. OSHA preliminarily concludes that no provisions of the rule pose technological feasibility problems for any potentially affected entities. This is the case because the standard emphasizes administrative controls, such as the early identification of suspected or confirmed cases of TB and employee information and training, rather than engineering controls. In

addition, the engineering controls that are required, such as AFB isolation rooms, biological safety cabinets, and temporary AFB isolation facilities, would be mandated only in those situations where individuals with suspected or confirmed infectious TB are admitted and isolated, where high hazard procedures are performed, and in situations where individuals cannot be placed into AFB isolation rooms within five hours of being identified as having suspected or confirmed infectious TB. All of the engineering controls required by the standard are currently available and in widespread use in many affected establishments.

Benefits of the Proposed Standard

Workers employed in the work settings covered by the standard are at significant risk of material impairment of health as a result of exposure to *M. tuberculosis* on the job. These workers will be the primary beneficiaries of the protection provided by the rule. However, because TB is a communicable disease, many other individuals will also benefit from the standard. Reducing the number of cases of TB among workers who are regularly in contact both with patients and infected members of client populations will reduce the incidence of TB infections and active cases in these client populations (since infected individuals spend the most time with other members of their group) and among members of the families of exposed workers. OSHA has expressed the benefits of the standard in terms of the numbers of TB infections, active cases, and TB-related deaths averted by the standard. In addition to reducing morbidity and mortality among workers, their families, and client populations, the standard will also generate readily quantifiable cost savings in the form of lower medical costs, less lost production, and reduced costs for administering workers' compensation claims and other private and social insurance system transactions.

OSHA's estimates of the potential benefits of the standard take into account the extent of current industry compliance with the provisions of the proposed standard, i.e., the benefits estimates do not include the benefits that employers in affected sectors are already garnering as a result of their voluntary efforts to provide protections to their TB-exposed employees. The benefits assessment presented in Chapter IV of the economic analysis is based on OSHA's Preliminary Risk Assessment (see that section of the preamble), which quantifies the occupational risk of TB infection among workers in hospitals, nursing homes, home health care work settings, and home care work settings. The estimates of risk are based on the rate of tuberculin skin test (TST) conversions among these populations. TST conversions are a widely used and well-documented index of TB infection; rates of conversion among the exposed populations are then compared with rates in unexposed or less-exposed ''control'' populations to obtain an estimate of the ''excess'' risk associated with occupational exposure. Table VII–2 shows the results of OSHA's estimates of the risks confronting workers in various work settings, based on statistical analyses and studies in the literature.

TABLE VII–2.—ESTIMATES OF OCCUPATIONAL RISK CONFRONTING WORKERS IN VARIOUS SETTINGS

Setting	Location and date	Excess risk (percent)	Estimated annual excess rate of TB infection per 1,000 workers
Hospital	North Carolina Western Region—1984–1985	398	5.7
Hospital	Washington State—1994	47	.68
Hospital	Jackson Memorial Hospital, Miami, Florida—1991	795	11.8
Nursing Homes	Washington State—1994	1019	14.6
Home Health Care	Washington State—1994	478	6.9
Home Care	Washington State—1994	112	1.6

Source: OSHA, Preliminary Assessment of Risk.

Where risk data of good quality were available for a specific industry, OSHA relied on that data. However, such data were available only for the hospital, nursing home, home health care, and home care industries. Accordingly, OSHA identified the best data to use to characterize the occupational risk of TB infection posed to workers in the other work settings covered by the proposed rule. After a careful review of the available data, OSHA chose to rely on data from western North Carolina that looked at occupational risk in a total of eight hospitals. These data were selected because they derived from hospitals that were relatively ''uncontrolled,'' i.e., that had not yet implemented many of the controls that would be required by the proposed standard. Data from the other hospitals shown in Table VII–2 were judged to be less appropriate for the purpose of extrapolation because Washington State hospitals are already generally in compliance with the requirements of the proposed rule and Jackson Memorial Hospital had recently experienced an outbreak of multi-drug resistant TB among its patients at the time the risk data were gathered. OSHA believes that using occupational risk data from hospitals to characterize the risk in other occupational settings for which risk data are unavailable is appropriate because employees in these other settings serve client populations that have a high incidence of active TB cases, perform high-hazard procedures, or visit hospitalized TB patients. The use of a hospital-based risk estimate results in a lower estimate of risk than would be the case if OSHA had used risk data from nursing homes or home health care to characterize the risk in other settings, but a higher risk than if OSHA had used risk data from the home care industry to do so.

To predict the effectiveness of the proposed standard, OSHA evaluated the reduction in occupational risk that various control measures required by the standard can be expected to achieve. Effectiveness is measured as the percent reduction in TST conversions and in the TB infections, active cases, and deaths represented by those conversions. Based on a thorough review of the available literature on the effectiveness of control programs that have actually been implemented in a number of hospitals, OSHA believes that the proposed standard, once implemented, would

reduce TB infections among occupationally exposed hospital workers by 90 percent, and would decrease such infections in the other work settings covered by the standard by 70 to 90 percent. OSHA also estimated the effectiveness and medical surveillance and follow-up in preventing infections from advancing to active cases of TB. OSHA found that such measures reduced the probability of an infection advancing to an active case by 35 to 47 percent, depending on the frequency of testing.

Using these effectiveness data, taking account of the current levels of compliance in various workplaces, and relying on the estimates of excess risk presented in OSHA's Preliminary Risk Assessment, OSHA predicts that the proposed standard will avert about 21,000 to 26,000 work-related TB infections per year, 1,500 to 1,750 active disease cases resulting directly from these infections, and 115 to 136 deaths directly related to the same infections. Preventing this number of infections among workers will, in turn, prevent about 3,000 to 7,000 infections, 300 to 700 active cases, and 23 to 54 deaths among the families, friends, clients, and contacts of these workers. In addition, the standard will annually generate cost savings of $89 to $116 million dollars in avoided medical costs, lost production caused by absence from work and other factors, and insurance administration costs. Table VII–3 shows the benefits of the proposed standard.

TABLE VII–3.—SUMMARY OF BENEFITS ASSOCIATED WITH THE PROPOSED STANDARD

Type of benefit	Work-related	Transmissions from work-related sources	Total number averted
Infections Avoided	21,380–25,769	2,954–6,978	24,334–32,747.
Active Cases Avoided	1,477–1,744	295–698	1,772–2,442.
Deaths Avoided	115–136	23–54	138–190.
Cost Savings	$80,721,000–$95,393,000	$8,614,000–$20,381,000	$89,335,000–$115,774,000.

Source: Office of Regulatory Analysis, OSHA, DOL.

Chapter V of the economic analysis projects the costs employers in the various industries covered by the standard are estimated to incur to achieve compliance with the rule's requirements. OSHA estimated costs for each covered industry and for each provision of the standard. These costs take account of the baseline levels of compliance prevailing in each industry at the present time and are presented as annualized costs discounted at 7 percent. Annualized costs are the sum of annualized initial costs and recurring annual costs. For example, a temporary AFB isolation room costing $4,095 with annual maintenance costs of $50 would have annualized costs of $633 ($583 + $50).

The total estimated costs of compliance for the standard as a whole are $245 million per year. The most costly provisions of the standard are those requiring medical surveillance and training for occupationally exposed employees. Together, these two provisions account for 60 percent of the costs of compliance. The two industries projected to incur the highest costs are hospitals and nursing homes. Together, the costs incurred by these two industries are estimated to be $138 million per year. Tables VII–4 and VII–5 summarize the annualized costs of compliance, by provision and industry, respectively.

TABLE VII–4.—TOTAL ANNUALIZED COSTS, BY PROVISION

Provision	Total annualized cost
Exposure Control	$12,858,183
Work Practice Controls	9,740,559
Transfers	9,740,559
Engineering Controls	22,529,248
AFB Isolation Rooms	7,547,912
Temporary AFB Isolation	10,792,678
Laboratories	780,270
Autopsies	2,903,077
Daily Testing of Negative Pressure	505,310
Respiratory Protection	45,771,276
Respirators	32,225,228
Respirator Program	1,670,677
Fit Testing	8,905,821
Evaluation of Program	2,969,549
Medical Surveillance	94,901,455
Medical History/Physical Exam	62,974,255
Tuberculin Skin Testing (TST)	21,907,252
Medical Management/Follow-up	4,773,377
Medical Removal	5,246,570
Communication of Hazards	52,268,172
Signs and Labels	58,284
Training	52,209,888
Recordkeeping	7,228,533
Engineering Control Maintenance	20,052
Medical	6,785,014
Training	423,467

TABLE VII–4.—TOTAL ANNUALIZED COSTS, BY PROVISION—Continued

Provision	Total annualized cost
Total	245,297,426

Source: U.S. Department of Labor, OSHA, Office of Regulatory Analysis.

TABLE VII–5.—SUMMARY OF COMPLIANCE COSTS, BY INDUSTRY

Provision	Total annualized cost
Hospitals	$61,819,637
Nursing Homes	76,500,314
Correctional Institutions	20,187,666
Immigration Detainment	145,378
Law Enforcement	6,708,174
Hospices	2,237,959
Homeless Shelters	11,287,278
Substance Abuse Treatment Centers	12,751,545
Medical Examiners	557,811
Home Health Care	16,448,605
Emergency Medical Services	4,981,780
Laboratories	1,696,383
Contract HVAC	396,197
Social Services	3,063,444
Physicians	5,663,949
Pulmonary Physicians	930,775
Personnel Services	18,363,135
Attorneys	1,557,398
Total	245,297,426

Source: U.S. Department of Labor, OSHA, Office of Regulatory Analysis.

Chapter VI assesses the economic impacts of the proposed standard on the industries affected by the proposed standard and also analyzes the impacts on the small businesses within each of these industries. OSHA preliminarily concludes that the standard is economically feasible for affected firms. On average, annualized compliance costs for all entities amount only to 0.06 percent of revenues and only 1.8 percent of profits. For all industries, costs as a percentage of revenues are less than 1 percent. For two industries, costs as a percentage of profits exceed 5 percent; these industries are substance abuse treatment centers and personnel services. OSHA does not believe, however, that these profit impacts will actually be incurred by facilities in these two sectors. Only 18.5 percent of substance abuse treatment centers operate on a for-profit basis. If substance abuse treatment centers can increase their revenues by as little as 0.34 percent, they can completely offset their compliance costs. The revenue increases or reductions in services needed to achieve cost passthrough are not expected to represent significant impacts for these facilities. The situation for personnel service firms is similar; these firms would have to increase the prices charged to their customers by as little as 0.56 percent to completely offset the costs of compliance. It is likely that these agencies will be able to pass such a small increase in costs through to their customers, i.e., to facilities purchasing personnel services. Table VII–6 shows compliance costs as a percentage of revenues, by industry.

TABLE VII–6.—SCREENING ANALYSIS TO IDENTIFY POTENTIAL ECONOMIC IMPACTS ON AFFECTED ENTITIES

Industry	Number of affected establishments	Percent of for-profit establishments in industry	Cost as a percentage of revenues
Hospitals	5,749	15.5	0.02
Nursing Homes	20,254	71.4	0.16
Correctional Institutions	2,079	0.0	0.10
Immigration Detainment	12	0.0	0.16
Law Enforcement	4,950	0.0	0.03
Hospices	1,755	12.0	0.09
Homeless Shelters	10,450	0.0	0.64
Substance Abuse Treatment Centers	9,730	18.5	0.34
Medical Examiners	100	0.0	0.28
Home Health Care	10,921	40.6	0.11
Emergency Medical Services	5,099	14.5	0.11

TABLE VII–6.—SCREENING ANALYSIS TO IDENTIFY POTENTIAL ECONOMIC IMPACTS ON AFFECTED ENTITIES—Continued

Industry	Number of affected establishments	Percent of for-profit establishments in industry	Cost as a percentage of revenues
Laboratories	851	100.0	0.13
Contract HVAC	300	100.0	0.17
Social Services	2,342	0.0	0.27
Physicians	21,698	95.0	0.03
Pulmonary Physicians	1,853	95.0	0.06
Personnel Services	1,426	100.0	0.56
Attorneys	2,306	89.8	0.10
Total	101,875	48.7	0.06

Source: U.S. Department of Labor, OSHA, Office of Regulatory Analysis.

OSHA has preliminarily concluded that the proposed standard will have a significant impact on a substantial number of small entities and has therefore, as required by the Regulatory Flexibility Act Amendments of 1996, conducted an Initial Regulatory Flexibility Analysis (IRFA). This analysis has identified significant impacts on the small entity portion of the hospital, nursing home, correctional institution, homeless shelter, substance abuse treatment center, contract HVAC, and personnel services industries.

For the purposes of this analysis, OSHA defines small for-profit entities using the Small Business Administration's (SBA's) Table of Size Standards. For businesses affected by the proposed standard, the SBA classifies entities with annual revenues of less than $5 million as small for all industries, with the exception of contract HVAC firms, for which entities with less than $7 million in annual revenues are classified as small.

A small not-for-profit entity is defined as any nonprofit enterprise that is independently owned and operated and is not dominant in its field. Based on this definition, all not-for-profit entities affected by the proposed standard are considered small.

Many of the affected industries consist almost entirely of public sector facilities, such as correctional facilities, immigration detainment facilities, law enforcement facilities, medical examiners' offices, and social service organizations. Several other affected industries include some government-owned facilities, such as hospitals, nursing homes, and emergency medical services. Under the Regulatory Flexibility Act, ''small governmental jurisdiction'' refers to governments of cities, counties, towns, townships, villages, school districts, or special districts with populations of less than 50,000. For most of the affected industries, information on the number of such entities was not readily available. Where data were unavailable, the number of small publicly-owned entities was estimated based on the average number of people served per employee in each industry, from which OSHA estimated the average employment size of establishments serving populations of less than 50,000. These entities are considered small for the purposes of this analysis. OSHA requests information on size standards for public-sector entities.

OSHA requests comment on these definitions and estimates of the number of small entities. The complete IRFA is presented in Chapter VI of the economic analysis, and is also presented here.

Initial Regulatory Flexibility Analysis

The Regulatory Flexibility Act, as amended in 1996, requires that an Initial Regulatory Flexibility Analysis contain the following elements:

(1) A description of the reasons why action by the agency is being considered;

(2) A succinct statement of the objectives of, and legal basis for, the proposed rule;

(3) A description of, and, where feasible, an estimate of the number of small entities to which the proposed rule will apply;

(4) A description of the projected reporting, recordkeeping and other compliance requirements of the proposed rule, including an estimate of the classes of small entities that will be subject to the requirement and the type of professional skills necessary for preparation of the report or record; and

(5) An identification, to the extent practicable, of all relevant Federal rules that may duplicate, overlap or conflict with the proposed rule.

In addition, a regulatory flexibility analysis must contain a description of any significant alternatives to the proposed rule that accomplish the stated objectives of applicable statutes (in this case the OSH Act) and that minimize any significant economic impact of the proposed rule on small entities.[3] This section of the analysis closes with a review of the recommendations of the SBREFA Panel concerning this proposed rule and discusses how OSHA has responded to these recommendations.

Reasons for the Proposed Rule

From 1985 to 1994, the number of active TB cases in the United States increased by 9.4 percent, reversing a 30-year downward trend. Although the number of cases reported to the CDC has declined over the past few years, TB remains a serious problem in the United States. In 1994, 24,361 active TB cases were reported to the Centers for Disease Control and Prevention (CDC), and TB was reported to have caused 1,590 deaths in that year alone (Ex. 7–283).

Transmission of *M. tuberculosis* is a recognized risk in several work settings. A number of outbreaks of this dreaded disease have occurred among workers in health care settings, as well as other work settings, in recent years. To add to the seriousness of the problem, some of these outbreaks have involved the transmission of multidrug-resistant strains of *M. tuberculosis*, a form of the disease that is often fatal.

Objectives of the Proposed Rule

The objective of this proposal is to reduce the risk of occupational exposure to *M. tuberculosis* in exposed working populations through the use of engineering controls, work practice controls, respiratory protection, medical

[3] The Regulatory Flexibility Act states that a Regulatory Flexibility Analysis need not contain all of the above elements *in toto* if these elements are presented elsewhere in the documentation and analysis of the rule. The Regulatory Flexibility Analysis should, however, summarize where these elements can be found elsewhere in the rulemaking record.

surveillance, training, signs and labels, and recordkeeping. Implementation of these measures has been shown to minimize or eliminate occupational exposure to *M. tuberculosis*, and thus to reduce the risk of TB infection among workers. The legal authority for this proposed standard is the Occupational Safety and Health Act, 29 U.S.C. 655(b).

Description of the Number of Small Entities

The proposed rule would cover 80,400 establishments operated by 67,116 small entities, as defined above. Of the 67,116 small entities, about 49 percent (32,605 entities) are for-profit small entities, 20 percent (13,622 entities) are publicly-owned, and 31 percent (20,889 entities) are not-for-profit. About 79 percent of the total number of affected establishments are operated by small entities. The proposed rule covers 48,804 establishments operated by 48,044 very small entities, defined as entities of all kinds employing fewer than 20 workers. Almost 48 percent of the affected establishments are operated by very small entities.

Description of Proposed Reporting, Recordkeeping and Other Compliance Requirements

Avoiding a One-Size-Fits-All Standard. Occupational TB occurs in a wide variety of settings, which means that the risk varies substantially, and control measures differ, from one facility to another. OSHA's proposed TB standard has been tailored to recognize these differences. With respect to the background risk of exposure, the OSHA standard distinguishes between work settings in counties that have had no cases of TB in one of the past two years and fewer than 6 cases in the other of the past two years, work settings in counties with one or more cases of TB in both of the past two years or that have had 6 or more cases of TB in one of the past two years, and work settings that have encountered 6 or more cases of TB in the past 12 months. In addition, the OSHA standard treats different types of exposure to TB differently. For example, the standard has different requirements for employers who own facilities that treat TB patients, employers whose client populations have high TB rates, employers whose employees (such as attorneys and social service providers) visit patients who have been identified as having suspected or confirmed cases of TB, employers whose employees engage in various high hazard procedures, employers whose employees provide maintenance for ventilation systems serving confirmed or suspected TB patients, and employers who provide personnel to treat patients in their own homes. In part because of these many distinctions, the SBREFA Panel found that the regulation was difficult for many employers to understand (Ex. 12). To make the tailoring of the standard to specific situations easier to see, OSHA has developed tables showing which provisions of the standard are most likely to apply to employers in different circumstances and in various affected sectors (see the Scope paragraph discussion in Section X of the Preamble, ''Summary and Explanation''). In addition, OSHA intends to provide extensive outreach when the standard is published in final form. OSHA solicits comments on other ways to avoid a ''one-size-fits-all'' standard while at the same time making the standard easier to follow. For example, would developing a flow chart and/or expert system that asks employers a series of questions and then directs employers to applicable requirements be an aid to affected small entities?

Description of the Proposed Standard. The proposed rule would require that employers develop and implement exposure control plans; institute work practice and engineering controls; provide respiratory protection in various situations; provide medical surveillance (e.g., tuberculin skin testing, medical histories, medical management, medical follow-up, medical removal); and communicate hazards through the use of signs, labels, and training. These proposed requirements are discussed in greater detail in the Introduction (Chapter I) of this analysis.

The proposed standard would also require that employers establish and maintain medical, training, illness/injury, and engineering control maintenance and performance monitoring records. All establishments affected by the proposed rule would be affected by these proposed requirements. However, only establishments with engineering controls would be required to maintain records of the maintenance and monitoring of engineering controls.

In estimating the cost of establishing and maintaining medical records, OSHA used the wage rate of a clerical worker with some knowledge of medical recordkeeping as the base wage. However, the knowledge required to perform such duties can be acquired by most clerical workers with little effort. All recordkeeping requirements included in the proposed rule could therefore be performed by the existing staff in any of the covered industries. A detailed description of the proposed requirements appears in the Introduction and in the Costs of Compliance chapters of this analysis.

Relevant Federal Rules That May Duplicate, Overlap, or Conflict With the Proposed Rule

On October 28, 1994, the Centers for Disease Control and Prevention (CDC) of the U.S. Department of Health and Human Services published ''Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-Care Facilities,'' which recommends that facilities adopt many of the requirements included in this proposed standard. CDC has also published guidelines for the prevention of transmission of TB in homeless shelters, long-term care facilities for the elderly, and correctional institutions. OSHA has consulted with CDC in developing the proposed standard, and the basic elements of the standard correspond to the basic elements in the CDC guidelines. However, the CDC publication is only recommendatory and is therefore not enforceable. OSHA's studies (see chapters IV and V) show that few facilities are following all elements of these guidelines. Further, many portions of the CDC guidelines are written in language that does not lend itself to enforcement even if the guidelines were made mandatory. For example, portions of the CDC guidelines for health care facilities suggest that the employer ''consider'' adopting certain controls. A fuller discussion of the similarities and differences between OSHA's proposed rule and the CDC's recommendations is provided in Section III of the Preamble, which describes the events leading to the proposed standard. Although the U.S. Public Health Service has overall responsibility for the control of TB in the U.S. population, OSHA is the only agency specifically mandated to address the problem of TB transmission in occupational settings.

The Health Care Financing Administration (HCFA) of the U.S. Department of Health and Human Services requires that facilities undergo an initial accreditation inspection prior to receiving Medicare and Medicaid funding. Such facilities include hospitals, nursing homes and other long-term care facilities, and clinical laboratories. Hospitals are reinspected annually, nursing homes every 15 months, and laboratories every two years. One of the requirements of such accreditation is the implementation of an infection control program. However, unlike the OSHA proposed rule, HCFA's requirements do not specify the elements that must be included in such

a program. HCFA may cite facilities with poor results for specific program deficiencies but does not have the authority to cite facilities for failing to include specific elements in their infection control programs, unless those program elements are specifically required by an OSHA standard. This means that in the absence of an OSHA TB standard, HCFA could not require implementation of specific controls. The proposed rule does not in any way conflict with HCFA requirements. Further, the existing HCFA requirements have not ensured that health care facilities adopt the elements of an effective infection control and have not prevented outbreaks of TB in this workforce.

One small entity representative to the SBREFA Panel suggested that the OSHA regulation might conflict with state and local requirements for skin testing and for tracing contacts of active cases of TB (Ex. 12). OSHA has considered this suggestion and believes there is no conflict. Some states do have rules covering TB testing and contact tracing, but most states do not. In 1993, only 18 states had requirements for TB screening of employees in medical facilities, and only 23 states had testing requirements for nursing home employees. Further, these requirements are sometimes not as stringent as those OSHA is proposing; for example, some states require only an initial skin test. Although 49 states require the investigation of reported cases of TB, only 29 states require contact tracing by health departments. In states where local health departments provide contact tracing, such contact tracing would constitute compliance with OSHA's requirements for contact tracing by employers. Employers merely need to assure that contact tracing takes place; they need not do the contact tracing themselves if others are available to do this job for them. Thus, there is no conflict between the OSHA standard and existing state requirements, nor do existing state laws obviate the need for a standard that requires TB testing of exposed employees and the investigation of reported TB exposures. However, OSHA solicits comment on the interaction of state rules regarding testing and tracing and the proposed standard.

One small entity representative was concerned with how medical removal protection and worker compensation programs would interact (Ex. 12). Medical removal protection requires that workers receive full salaries, full benefits, and no loss of job position or seniority while the employee is unable to work, or unable to work at his/her usual position, as a result of incurring an occupational case of TB. The purpose of medical removal protection is to assure that workers provide timely and accurate information to their employers concerning their medical symptoms. In the absence of medical removal protection, workers have financial and job security incentives to avoid reporting symptoms. OSHA counts any payments workers receive from workers' compensation toward the goal of assuring medical removal protection; that is, employers may deduct from the amount they pay out to the worker any monies paid to the ill worker by workers' compensation. Workers' compensation is not an adequate substitute for medical removal protection because workers' compensation does not fully replace lost wages and provides no guarantee of maintenance of seniority, job security, current position, or non-wage benefits. Medical removal protection requires the employer to provide any of these elements that are not a part of workers' compensation. Thus, the employer of a worker already receiving workers' compensation would need to provide an additional salary increment in order to restore the employee's full salary and would need to provide the worker his or her full non-wage benefits.

One small entity representative expressed concern over a possible conflict between the proposed rule and Federal Confidentiality Regulations covering chemically abusive or dependent clients participating in licensed and federally-funded programs [Ex. 12]. These regulations prohibit disclosing information regarding the identification of a patient as a substance abuser without the patient's consent. This representative noted that, without patient consent, a disclosure may be made only to medical personnel to meet a situation that has been declared a medical emergency by the Surgeon General. This small entity representative was referring to Public Health regulations: Confidentiality of Alcohol and Drug Abuse Patient Records, 42 CFR 2, and a similar state statute: Confidentiality of Records, Minnesota Statute 254A.09. Both the Federal Confidentiality Regulations and the state statute cover records that would identify a patient as an alcoholic or drug abuser or concern his or her prognosis, diagnosis, treatment, attendance, status or physical whereabouts. No requirements of the standard would require the disclosure of records of this kind. These are not the kinds of records that are relevant to determining whether an individual has suspect or confirmed infectious TB. In addition, a medical referral for the client who is exhibiting signs and symptoms of TB can be made without revealing any of the prohibited confidential information. Moreover, in the case of an exposure incident, the identity of the individual with suspected or confirmed infectious TB need not be told to employees. Records maintained by employers on their employees are not covered by the regulations or statute, but would be subject to the same confidentiality requirements that govern all medical records. The identification and notification requirements in the proposed TB standard are the minimum necessary to prevent transmission of TB to employees. The contagious nature of the disease mandates early detection and early monitoring of individuals who have had an exposure incident.

One small entity representative to the SBREFA Panel expressed concern over possible interactions between the proposed standard and the Family and Medical Leave Act (FMLA) (Ex. 12). The Family and Medical Leave Act does not provide for leave with pay, and does not guarantee the continuation of any benefits other than health insurance. Further, the Family and Medical Leave Act covers a more limited timeframe (12 weeks) than the proposed standard's medical removal protection provisions (18 months). Thus, the only overlap between the proposed standard and the FMLA would occur in the area of health insurance benefits in the first 12 weeks of the worker's absence from work. Since the standard would specifically allow the employer to deduct from medical removal protection benefits any benefits paid to the worker from other sources, employers would not pay for the same benefits twice.

One small entity representative felt that the Americans with Disabilities Act (ADA) may offer protection to the ''worker who becomes ill as a result of an occupational exposure or who cannot work because of an inability to wear a PR [respirator].'' (Ex. 12) The ADA prohibits employers of 15 or more employees from discriminating, because of the disability, against a qualified individual with a disability with regard to terms, conditions and privileges of employment. An employer must provide reasonable accommodation for known physical or mental limitations for a qualified individual with a disability, unless accommodation can be shown to impose undue hardship on the employer. OSHA representatives noted that there is no conflict between an OSHA standard and the ADA requirements prohibiting discrimination. The ADA says that:

Nothing in this Act shall be construed to invalidate or limit the remedies, rights and procedures of any Federal law * * * that provides greater or equal protection for the rights of individuals with disabilities that are afforded by this Act. 42 U.S.C.A. 12201(b).

Further, the ADA would not provide the same protections as medical removal protection. In order for an employee to take advantage of the provisions of the ADA, certain conditions must be met. For example, the employee must work for a covered employer and be a qualified individual with a disability, i.e., one who can perform his or her job with or without reasonable accommodation. Thus, while the ADA may offer some protection to an employee who has or is suspected of having infectious TB or who cannot work because he or she cannot wear a respirator, the protection proposed to be provided by the OSHA standard for TB is more comprehensive and will lead to greater participation in the entire medical surveillance program. The OSHA proposed standard, in paragraph (g)(5)(ii), would provide to the employee with suspected or confirmed infectious TB:

* * * his or her total normal earnings, seniority, and all other employee rights and benefits, including the employee's right to his or her former job status * * * until the employee is determined to be noninfectious or for a maximum of 18 months, whichever comes first.

For each employee who must be removed for his or her job because he or she cannot wear a respirator (paragraph (g)(5)(iii)), the employer is required to:

transfer the employee to comparable work for which the employee is qualified or can be trained in a short period (up to 6 months), where the use of respiratory protection is not required [and] * * * maintain the total normal earnings, seniority, and all other employee rights and benefits. If there is no such work available, the employer shall maintain the employee's total normal earnings, seniority, and all other employee rights and benefits until such work becomes available or for a maximum of 18 months, whichever comes first.

OSHA's MRP provisions provide each employee, who must be medically removed, with the level of protection that is needed to assure that the employee promptly reports his or her symptoms of TB (which makes the workplace safer for all employees) and reports his or her difficulty with wearing a respirator (which makes the workplace safer for that employee).

Significant Alternatives to the Rule Considered by OSHA

This section first considers alternatives that OSHA was urged to consider by the SBREFA Panel and then turns to other alternatives considered by the Agency.

Alternatives Suggested by SBREFA Panel Members

Small entity representatives and SBREFA Panel members suggested a wide variety of possible clarifications and alternatives to the regulation. In response to these suggestions, OSHA has made a number of changes to the regulation, clarified the meaning of many sections of the rule, provided additional analysis, and added tables to the Preamble designed to clarify the requirements of the rule in various situations. A full discussion of OSHA's responses to all of the SBREFA Panel recommendations is given in the next section. This section only presents alternative approaches to the proposed rule and a discussion of the extent to which OSHA has adopted these alternative approaches. OSHA welcomes comments on these and other alternatives and on ways OSHA could adopt additional aspects of these alternative approaches and still meet the requirements of the OSH Act, particularly that Act's requirement to control significant risk to the extent feasible.

Less Stringent Trigger Mechanisms for the More Burdensome Portions of the Standard, Including Raising the Zero-Case Per County Per Year Trigger

OSHA has re-examined each provision of the proposed standard to ensure that it is necessary and appropriate to reduce risk. In the draft of the proposal reviewed by the Panel, OSHA required that a facility would only be eligible for the reduced TB control program requirements of Appendix A if the facility did not treat TB patients and if there had been no cases of TB in the county or the facility in the previous year. In its review, OSHA found that applying the standard's Appendix A requirements to facilities in counties with no TB cases in one of the last two years and fewer than 6 TB cases in the other of the last two years would not substantially increase the risk to employees in facilities located in such counties. This change from the trigger OSHA originally considered increases the number of counties qualifying for the Appendix A program from 43 percent to 55 percent of all U.S. counties.

Consider Allowing Portability of Training

The draft proposal reviewed by the SBREFA Panel required that all new employees be provided complete training. OSHA has examined its training provisions and decided that the non-site-specific components of training, such as training in the difference between tuberculosis infection and disease, can be transferred between employers without reducing the protection such training affords employees.

Do Not Require Annual Retraining

The draft proposal reviewed by the SBREFA Panel required annual retraining of all employees. OSHA believes that some method of assuring continuing competency is necessary, and that one-time training will not provide such assurance. However, the proposal now would allow employers to develop methods of assuring the competency of their employees, such as asking them questions about procedures, controls, etc., as an alternative to retraining. This change in the regulation will result in cost savings of $20 million per year.

Cooperative Initiatives, Such as Expanding OSHA's Current Cooperative Initiative With JCAHO

Some Panel members felt that cooperative initiatives could substitute for regulation in some areas. As noted above, however, in the absence of an OSHA standard, HCFA (and accrediting associations working with HCFA, such as JCAHO) does not have the authority to enforce specific infection control requirements. As a result, a cooperative initiative alone would leave employees exposed to TB in hospitals, who account for 13 percent of the active cases of TB projected to be prevented by the standard, without any new initiative designed to prevent these active cases of TB. If this approach were extended to nursing homes, and all nursing homes chose to be accredited, then 70 percent of the active cases of TB projected to be prevented by the standard would be denied coverage. Thus, OSHA does not feel that cooperative initiatives, even with accrediting organizations, can substitute for regulation.

Others suggested that OSHA could turn over enforcement of any TB regulation to HCFA, JCAHO or another accrediting or standards organization. In the eyes of its proponents, the suggestion that others could enforce OSHA's regulation has several major advantages. First, it would assure regular and more frequent inspections at health care facilities and nursing homes than OSHA alone could provide. Second, it would require health care facilities and nursing homes to deal only with a single inspection for infection control procedures, rather than

inspections by two different federal agencies. Third, these organizations may have greater penalty powers than OSHA, in that denial of HCFA acceptance or of accreditation can result in a health care facility losing significant funding or even being required to close.

For several reasons, providing exclusive HCFA enforcement of OSHA's TB requirements is an unsound approach. First, OSHA inspectors already inspect health care facilities, just as they inspect any other facility covered by the OSH Act, for possible violations of any OSHA requirement, e.g., safety as well as health requirements. The need for these OSHA inspections would not change even if HCFA or accrediting agencies enforced OSHA's TB requirements. Second, OSHA does not believe that it is legally appropriate under the OSH Act to tell its inspectors that, when they inspect health care facilities, they must ignore violations of the Agency's occupational exposure to TB requirements. Third, OSHA also cannot legally ignore employee complaints relating to occupational exposure to TB. For all of these reasons, OSHA believes that exclusive enforcement of the rule by HCFA or by agencies, such as JCAHO, that are authorized to provide accreditation, is not an appropriate or legally defensible approach.

However, OSHA does favor expanding its cooperative agreements, such as the current agreement with JCAHO, in any ways that both agencies agree would be beneficial, and OSHA is currently pursuing this option. On August 5, 1996, OSHA and JCAHO announced a 3-year partnership to promote health and safety for healthcare workers. This partnership will help health care facilities to meet accreditation expectations and OSHA compliance requirements. The initiatives of this partnership will include cataloging and evaluating duplicative compliance activities; undertaking cross-education and training of JCAHO and OSHA staff on corresponding requirements that relate to the management of worker safety and health; and developing a series of collaborative publications and user education programs.

A Federal-State Government Public Health Partnership to Develop Guidelines in Various Industry Sectors

The CDC is already charged with developing guidelines for the control of TB, and has already issued guidelines for correctional institutions, laboratories, health care facilities, long-term care facilities for the elderly, and homeless shelters. In fact, OSHA has made extensive use of these guidelines in developing its proposed occupational exposure to TB standard. OSHA feels that the CDC guidelines alone have not served adequately to protect TB-exposed workers, however. OSHA research indicates that the CDC guidelines are not being followed in most facilities, and believes that this is the reason that occupational exposure to TB remains such a serious problem in this country. In Chapter VII of the analysis, OSHA shows that these guidelines are not being followed and explains why many employers have little economic incentive to implement these guidelines.

Performance Standards Developed With the Assistance of Federal, State, and Local Government, and Labor and Industry

OSHA feels that its standard is a performance oriented standard that has benefited from both CDC's expertise and from many stakeholder meetings (which include representatives of other federal, state and local government agencies, labor, and industry) and the SBREFA Panel Process.

OSHA's proposed standard is performance oriented in a variety of ways. For example, OSHA does not specify procedures by which facilities must achieve AFB isolation, but instead allows any workable design. Similarly, OSHA sets performance criteria for respirators, but does not specify the types of respirators that must be used. OSHA does specify procedures for identification of suspect cases, but allows any method that assures that persons with the appropriate symptoms are identified as suspect cases. However, OSHA did not consider it appropriate to specify performance in terms of rates of TB cases or TB skin test conversions. Such an approach is not preventive, in that application of proper procedures would only occur after TB infection had occurred. Furthermore, most smaller facilities do not have enough TST conversions for statistically meaningful trends to be established. OSHA requests comments on this issue.

Some proponents of this approach feel that OSHA's proposed standard may not reflect the best ideas for controlling occupational exposure to TB and argue that stakeholder meetings would be a useful way of developing a better approach. OSHA held five stakeholder meetings involving representatives from more than thirty interested organizations. Furthermore, the CDC has made use of the best expertise in the country in developing its guidelines, and OSHA has adopted most elements of these guidelines and will hold public hearings on the standard at which interested parties can present their views. OSHA welcomes comments about alternative approaches to reducing occupational exposure to TB, particularly suggestions concerning more performance oriented approaches, but feels that this proposal is the result of an extensive review of the literature and of input from stakeholders on the available prevention and control methods and should be issued as a proposal at this time to prompt further discussion and exchange of information. OSHA is particularly interested in alternative methods of identifying suspected cases of TB and in whether the proposed requirements would preclude or impede programs that employers have found to be effective.

Separate Approaches for Health and Non-Health Industries The Approach for Health Industries Should Be Keyed to Existing Industry Standards and That for Non-Health Industries to Guidelines

This suggested alternative incorporates several concepts. First, it assumes that the health and non-health care sectors should be given separate treatment because of differences in existing regulations and expertise. OSHA agrees that sectors that differ in relevant ways should be given different treatment, and the standard therefore has provided for different approaches to different sectors. For example, OSHA's standard does treat facilities that treat TB patients differently from the way it treats those that transfer TB patients out of their facilities, and treats employers whose employees are routinely in contact with client populations with high rates of infectious TB (such as homeless shelters and drug abuse treatment centers) differently from employers whose employees only come into contact with infectious TB cases on an occasional basis (such as attorneys and social workers).

Second, this alternative posits that the health care sector is already subject to an extensive regulatory system with respect to occupational exposure to TB. Although some states have laws on contact tracing and skin testing, and HCFA inspects infection control systems in hospitals and long-term care facilities for the elderly, there are no existing enforceable standards aimed specifically at occupational exposure to TB. Thus OSHA's proposed provisions with respect to preventive measures have no equivalent in existing regulations, and only a limited number of states require skin testing of the kind OSHA's proposed standard requires. OSHA (and CDC) believes that these

provisions are essential to any program to control occupational exposure to TB. Third, proponents of this alternative believe that the non-health care sectors, particularly those engaged in charitable work such as homeless shelters, are better approached through guidelines than regulations. OSHA believes that there is relatively little need to develop guidelines for non-healthcare sectors, such as correctional institutions and homeless shelters, because such guidelines already exist and have not been implemented in many, if not most, facilities. Some proponents of this approach believe that the failure of non-health care sectors to implement existing guidelines is due to the absence of outreach and information. OSHA is not substituting a system of regulation for a system of outreach. OSHA intends to continue a program of outreach on occupational TB, and hopes that facilities in all sectors will adopt appropriate policies before the regulation is finalized. However, given that even in the relatively knowledgeable health care sector, implementation of the CDC guidelines has been limited, it is unlikely that outreach alone can assure the full implementation of suitable measures for control of occupational exposure to TB.

Different Levels of Requirements for Different Industries, Depending on Their Expertise, Resources, and Risk

OSHA's proposed standard recognizes three levels of risk and provides separate treatment for employers engaged in different kinds of activities, where those differences are relevant to the purposes of the standard. This subject is discussed in the next sections. Such tailoring, however, must be consistent with the mandate of the Occupational Safety and Health Act to reduce significant risk to the full extent feasible. OSHA has preliminarily found all of the standard's provisions to be technologically and economically feasible, within the meaning of the Act, for facilities in all affected industries. (The special potential problems of homeless shelters and substance abuse treatment centers are discussed further below.) The statutory requirement to eliminate significant risk to the extent feasible means that if inadequate resources and expertise would make any provision of the proposed standard infeasible, then OSHA would have to consider alternative approaches. However, it also means that the resources and expertise that are feasible for an employer to acquire must be employed if they will reduce significant risk.

Separate Standards for Each Affected Industry

Proponents of this alternative had two goals: first, to assure that OSHA gave full consideration to the circumstances of each affected industry, and second, to make the standard easier to follow for affected small entities. With respect to the first goal, OSHA has recognized a wide variety of distinctions in risk of exposure and practice among affected employers. Some of these differences follow industry lines. Accordingly, the proposed standard includes special provisions for laboratories and home health care providers. However, most of the relevant differences among employers do not strictly follow industry lines, and attempts to write separate standards for different industries would not significantly reduce the complexity of the regulation. For example, all industries need to realize that different requirements are applicable for each of three types of risk of exposure. Similarly, the applicability of certain requirements depends on whether TB patients are treated onsite and on whether certain hazardous procedures are performed. While, for example, the typical nursing home would not treat TB patients or perform high hazard procedures on site, some might, and thus these provisions would need to be included in an industry standard written for nursing homes. OSHA's proposed standard carefully distinguishes a variety of activities that may occur in different industries and has different requirements for each activity. Although this makes the standard somewhat more complex, this approach is essential to avoid a ''one size fits all'' standard. In addition, as presented in the discussion of the scope in the Summary and Explanation of the Preamble, OSHA has developed charts showing the requirements of the proposed standard that are applicable to each industry. OSHA welcomes any suggestions on ways to make the standard easier to understand, or on ways to adapt the standard to the situation of specific industries while reducing significant risk.

Revise the Proposed Standard for Consistency With CDC Guidelines

The issue of how the CDC Guidelines fit into a regulatory scheme to prevent or reduce occupational exposure to TB has been considered by OSHA and other reviewers. OSHA's view is embodied in the proposed standard, in which the Agency has attempted to translate the CDC's recommendations into enforceable regulatory language that can be applied to a variety of occupational settings where the risk of transmission of TB is significant. The Agency believes that, in addition to the basic difference between a ''guideline'' and a ''regulation,'' there are only three general areas where the proposed standard differs substantially from the CDC Guidelines for health care facilities: the use of site-specific risk assessment, the frequency of skin testing in certain situations, and the required use of respiratory protection around unmasked individuals with suspected or confirmed infectious TB. Several small entity representatives, along with some SBREFA Panel members, have suggested that the Agency consider allowing employers to follow the CDC Guidelines as an additional option to comply with the OSHA standard.

Both the OMB and SBA Panel representatives believe that for at least some of the work sites OSHA has proposed to cover, the CDC Guidelines currently provide an adequate measure of protection. They believe it would be burdensome for employers who are already in compliance with the Guidelines to have to become familiar with the OSHA proposal and to implement its provisions. These employers have already invested in a TB prevention and response program consistent with the Guidelines. In other words, the employers have conducted their risk assessments, implemented the suggested provisions and trained their workers to comply. Moreover, these reviewers point out that where the Guidelines have allowed for discretion on the part of the employer as, for example, where an employer may first consider the symptoms specified in the several CDC Guidelines' definition of ''suspected infectious TB'' before adopting a definition for his or her own work site, prevention of the transmission will more easily be achieved because the employer is allowed to tailor the requirements to actual conditions in his or her workplace. To assure that the employer's adoption of the CDC Guidelines is effective, these reviewers recommended that the employer assert or certify that he or she is in compliance and, if challenged in an OSHA inspection, prove the efficacy of his or her program through a performance measure, such as skin test conversion rates. These reviewers believe that this approach will result in a more efficient use of scarce health resources.

OSHA agrees that the various CDC Guidelines are the most important sources for setting an occupational health standard that will reduce or prevent the spread of TB. However, although certain facilities adhere to the

Guidelines, OSHA's research has shown that most facilities have not fully implemented the CDC recommendations. TB remains an occupational hazard, and OSHA has preliminarily concluded that the risk of transmission of TB to employees is significant. OSHA believes there are a number of reasons why the Guidelines cannot take the place of an OSHA standard. First, the Guidelines are not written in language that can be enforced. For example, the Guidelines suggest, recommend and set forth what an employer could or should do, not what he or she must do. Unless the Guidelines are converted to regulations, an employer may adhere to some applicable recommendations while not implementing others, which could result in uneven and inadequate employee protection. OSHA standards are written in mandatory language, letting employers and employees know what they have to do in order to be in compliance with the regulation. This permits an employer, an employee or a compliance officer to determine easily whether an entity is in compliance with a standard. Second, the establishment-specific risk assessment approach of the Guidelines imposes a tremendous paperwork burden on covered entities and requires a level of professional expertise in risk assessment that few entities outside of large hospitals possess. OSHA believes that recommendations or regulations that necessitate this level of expertise could make it difficult to determine if an entity is in compliance. Third, OSHA knows of no objective criterion that could be reliably used as a measure of proof of an effective program. Tuberculin skin testing has been suggested as a means of proving compliance with the CDC Guidelines, e.g., zero conversions would be accepted as proof that an entity was complying with the Guidelines. However, the use of conversions as a compliance measurement has two problems. First, skin test conversions are not necessarily indicative of implementation of the Guidelines' recommendations. For example, an entity may have implemented very few of the Guidelines' recommendations, yet been fortunate enough to experience no conversions. Therefore, compliance with the Guidelines' recommendations has not been achieved even though there have been no employee conversions. Furthermore, while an increase in the number of conversions indicates employee exposure, a lack of conversions does not necessarily mean that employees are not being exposed. For example, some employees have already skin-tested positive, not all exposures result in conversions, and many entities will not have enough TST-negative employees to generate sufficient statistical power to accurately determine an increased conversion rate. With regard to this last point, the CDC states:

> A low number of HCWs in a specific area may result in a greatly increased rate of conversion for that area, although the actual risk may not be significantly greater than that for other areas. Testing for statistical significance (e.g., Fisher's exact test or chi square test) may assist interpretation; however, lack of statistical significance may not rule out a problem (i.e., if the number of HCWs tested is low, there may not be adequate statistical power to detect a significant difference). Thus, interpretation of individual situations is necessary. (Ex. 4B)

Second, OSHA believes that reliance on number of TST conversions as a performance measure is reactive rather than proactive, because it emphasizes the identification of employees who have already incurred a status change as a result of an exposure instead of averting exposures.

OSHA believes that compliance with the proposed standard by all affected facilities within the covered sectors is the way to assure that employees will be protected from occupational transmission of TB. The Agency believes that compliance will not be difficult for employers who have already implemented the Guidelines, because many of the elements of the Guidelines have been incorporated into the proposed standard. Also, employers who are not in compliance with the Guidelines will find that the standard gives them clear instructions on what to do. In addition, the structure of OSHA's proposed TB standard is similar to that of the Bloodborne Pathogens standard (BBP). Since the vast majority of workplaces that will be covered by the TB standard are subject to BBP, becoming familiar with and implementing the requirements of the TB standard should not be difficult.

Another issue raised in the review process was what would happen if, after the OSHA standard was promulgated, the CDC issued a new guideline that was different from the OSHA standard on an item addressed by the standard. OSHA believes this is already addressed by OSHA's citation policy, in particular, the policy for De Minimis Violations, which states that violations of standards which have no direct or immediate relationship to safety or health are not to be included in citations. An example of a de minimis violation occurs when an employer complies with a proposed OSHA standard or a consensus standard rather than with the OSHA standard in effect at the time of the inspection and the employer's action clearly provides equal or greater employee protection [OSHA Field Inspection Reference Manual, Instruction CPL 2.103, September 26, 1994]. In cases where an employer is complying with another provision, such as a consensus standard, the Agency looks at the consensus standard to make sure the consensus standard is at least as protective as the OSHA standard. Because CDC Guidelines reflect the views of many of the country's leading experts and practitioners in public health measures to prevent the spread of TB, the updated CDC Guidelines can be assumed to provide equal or greater protection against occupational transmission of TB to employees. Because these guidelines carry great authority, the De Minimis Violation policy would not only be a defense, but would be accorded such deference that OSHA would incur a heavy burden in showing that an updated CDC guideline on an item addressed by the OSHA TB standard did not provide equal or greater protection against occupational transmission of TB to employees. In order to ensure that the new CDC Guidelines would be communicated to the OSHA Regions and others who would need to know, OSHA will issue a Memorandum for Regional Administrators that will address how the new Guideline could be implemented in the work place, include a copy of the new Guideline, and instruct the Regional Administrator to contact area offices and the OSHA state designees. In addition, the Memorandum would be posted on the OSHA Computer Information Service (OCIS) and OSHA CD–ROM, which are accessible to the public.

OSHA seeks comment on all issues related to the CDC Guidelines, particularly whether they could be implemented in lieu of an OSHA standard and, if so, how compliance and efficacy could be determined.

Change the Approach to the Identification of Suspect Cases for Homeless Shelters or Substance Abuse Treatment centers

The SBREFA Panel found that ''Given the current definition of suspect cases, it is not clear that homeless shelters can comply fully with the standard. Accordingly, OSHA should reexamine the definition of suspect cases and/or reexamine its approach to homeless shelters.'' The SBREFA Panel also noted that this same finding might be relevant to substance abuse treatment centers. The Panel arrived at this finding as a

result of statements made by small entity representatives from the homeless shelter sector. Small entity representatives concerned with homeless shelters had serious problems with OSHA's definition of a suspect case and questioned the feasibility of screening the homeless by using questions about symptoms. Mr. Wayne Anderson of the National Health Care for the Homeless Council argued that OSHA's definition of a suspect case would result in the identification of most of the homeless as suspect cases during the winter months. Major Dalberg of the Salvation Army found OSHA's definition of a suspect case confusing and ambiguous, and stated that it would cover a substantial portion of the homeless. All three small entity representatives from this sector questioned whether the standard's screening procedures were workable in the homeless shelter context. They asserted that the homeless might avoid screening questions, be unable to answer them, learn how to lie in response to such questions, or choose to remain on the street rather than be transferred to a hospital. The small entity representatives for this sector felt that this portion of the standard should be abandoned. Because substance abuse treatment centers serve a similar clientele, the Panel was concerned that the same problems might apply to substance abuse treatment centers.

To address this issue, and other issues related to the feasibility of the proposed standard for homeless shelters, OSHA has decided to hold special sessions during the public hearings on the proposed standard and to study these issues further through an onsite survey of a number of homeless shelters. The study will address the following issues:

- Percentage of homeless persons that would be identified by OSHA's definition of a suspected infectious TB case. (Breakdown of which symptoms are particularly common so a better definition might be designed.)
- Turnover among the homeless who use shelters.
- Employee turnover in homeless shelters.
- Trends in number of homeless persons served in shelters.
- Criteria currently used by some homeless shelters to identify suspected infectious TB cases.
- Current practices used in homeless shelters to address the TB hazard (baseline compliance with the draft proposed standard).

—Methods of isolation.

—How suspected TB cases are handled.

- Feasibility of having hospitals provide cards to the homeless indicating TB skin test status.
- Number of TB skin test conversions and active cases among the homeless and homeless shelter employees.
- Types of benefits offered to homeless shelter employees (e.g., health insurance).
- Economic feasibility:

—Costs of running a shelter.

—Revenue sources.

—How costs are accommodated as the number of homeless persons served increases.

—Opportunities for cost pass-through.

- Number, location and types (e.g., family-oriented, walk-in, all-male) of homeless shelters.
- Number or proportion of homeless shelter workers who are unpaid volunteers.

The study will also address the issue of volunteers. The OSH Act applies to employees, not bona fide volunteers; however, OSHA understands that some states may, as a matter of state law, require facilities to provide volunteers with the protections established by OSHA standards. Thus, OSHA's study will address the following issues:

- Economic impacts, in such states, of covering volunteers (e.g., how costs would be handled, cost pass-through opportunities).
- Protections currently offered to volunteers.

The results of the study will be made available for comment in the public record.

OSHA does not feel that the same problems apply to substance abuse treatment centers, even if a high percentage of clients might be defined as suspect cases. Inpatient substance abuse treatment centers routinely provide some form of entrance physical: this would be an appropriate time to screen for suspect cases and provide for their referral.

Outpatient substance abuse treatment centers do not provide any form of shelter for patients, and thus could readily refer suspect cases to a hospital without either denying them shelter or having to pay for the referral. Such a facility could simply insist that suspect cases not return without data showing that they had been to a doctor and did not have TB. Since outpatient facilities handle a known population, such an approach might involve high initial referrals, but could thereafter settle into a system that checked for suspect cases on entry to the program.

OSHA estimates that the proposed standard will result in a reduction of 28 to 33 active disease cases and 2 to 3 deaths per year in the homeless shelter sector. A standard requiring skin testing and follow-up treatment alone would have only one third the benefits (such an approach would reduce the number of active disease cases to only 10 per year and the number of lives saved to 1 per year). The annual costs of the proposed standard for homeless shelters are estimated to be $11,287,278, or approximately $1,080 per shelter per year.

OSHA solicits comments on all of the issues listed above to be covered by its study of homeless shelters, and solicits comment on the feasibility of the standard for substance abuse treatment centers, and particularly on the extent to which substance abuse treatment centers already provide for medical examinations prior to entry into their programs.

Other Alternatives Considered by OSHA

OSHA considered several additional alternatives but has preliminarily concluded that the proposed rule will better carry out the objectives of the OSH Act, while minimizing the economic impact on affected establishments, and especially on small establishments. OSHA requests comment on the validity of this preliminary conclusion. First, OSHA considered making all of the proposed requirements applicable to every establishment in the covered industries. The prevalence of TB, however, varies by geographical areas and by the populations served by facilities in different industries. OSHA therefore believes it will be possible to reduce significant risk without imposing the full regulatory requirements on each covered employer. Second, OSHA considered proposing requirements similar to the CDC's guidelines, which recommend that risk assessments be conducted to determine the level of risk in each facility and that the controls implemented vary in accordance with the level of risk in each facility. This would require that employers conduct risk assessments by evaluating factors, such as the number of suspected or confirmed TB cases among patients and employees, employee tuberculin skin testing results, and the amount of TB in the community. The CDC recommendations include five levels of risk (i.e., minimal, very-low, low, intermediate, and high), and the recommended controls vary by the level of risk. However, adopting such a requirement in the OSHA standard would impose a large cost and a heavy paperwork burden on affected facilities.

To avoid imposing unnecessary burdens on facilities where the risk of

occupational exposure to *M. tuberculosis* may be lower, OSHA is proposing to exempt facilities from certain requirements (i.e., respiratory protection, annual medical histories, and annual skin tests) if the facility transfers, instead of admits, individuals with suspected or confirmed infectious TB and can additionally demonstrate that there have been (1) no reported confirmed infectious TB cases in the county within one of the last two 12-month reporting periods; (2) fewer than 6 infectious cases of TB in the other 12-month reporting period; and (3) no infectious cases of TB encountered within their employees' work settings within the past 12 months.

OSHA also considered proposing a requirement that facilities implement engineering controls in all intake areas in which early identification procedures are performed, if the facility had encountered six or more individuals with confirmed infectious TB in the past 12 months. The engineering controls considered were single-pass ventilation, filtration of air through the use of HEPA filters installed as part of the ventilation system, or stand-alone auxiliary HEPA filtration units. However, areas where early identification procedures are performed vary widely in size and configuration, making it difficult to assess the effectiveness of such controls in reducing the risk of occupational exposure to *M. tuberculosis* in a particular setting. Given the high cost of such controls and the lack of data on their effectiveness, OSHA is not proposing such a requirement. However, the Agency requests comment on the potential effectiveness of such controls in intake areas.

Another alternative considered was to propose that each occupationally exposed employee be provided with a baseline medical examination, including a physical examination that emphasized the pulmonary system and an evaluation for the signs and symptoms of active TB disease and factors affecting immunocompetence. However, requiring a baseline physical examination for all exposed employees would impose a heavy cost burden on affected establishments, and OSHA could find no evidence that providing a baseline physical examination would accomplish more than a baseline and annual medical history and tuberculin skin test in identifying or reducing occupationally induced TB infections. Thus, OSHA is proposing to require physical examinations only when they are deemed necessary by the physician or other licensed health care professional, as appropriate.

OSHA also considered providing medical management and follow-up to each employee who had been exposed to air originating from an area where an individual with suspected or confirmed infectious TB was present. However, stakeholders contacted prior to the issuance of this proposal stated that a requirement for medical management and follow-up would impose an unnecessary burden on affected establishments for those cases that were suspected but were subsequently ruled out. In response to stakeholders' comments, the Agency is proposing that medical management and follow-up be provided only when an employee is actually exposed to an individual with confirmed infectious TB or to air containing aerosolized *M. tuberculosis* without the benefit of the applicable exposure control measures (e.g., respiratory protection) that would be required under the proposed rule.

Another alternative considered was to require tuberculin skin tests every six months for all employees assigned to wear respirators. However, to reduce the burden on facilities that do not encounter many infectious TB cases, OSHA is not requiring 6-month skin testing for workers assigned to wear respirators and who work in the intake areas of facilities where fewer than six confirmed infectious TB cases are encountered each year.

Rejecting these regulatory alternatives has reduced the estimated costs of the proposed rule by a minimum of $100 million.

The RFA emphasizes the importance of performance-based standards for small businesses. OSHA considers the proposed standard to be highly performance oriented. The proposed standard emphasizes the early identification and isolation of individuals with suspected or confirmed infectious TB. Affected employers have been allowed wide discretion in the selection of procedures they use to achieve this. Without early identification and isolation, prevention of the spread of TB from patients and clients to workers is virtually impossible. OSHA has also limited requirements for work settings located in a county that, in the past 2 years, has had zero cases of confirmed infectious TB reported in one year and fewer than 6 cases of confirmed infectious TB reported in the other year. OSHA welcomes comment on other ways that the standard can be made more performance oriented.

Another approach considered is compliance date phase-ins for small businesses. OSHA is proposing to extend the standard's compliance deadlines for engineering controls and has considered extending the compliance deadlines for the other proposed requirements; however, since these other requirements are not capital-intensive for most affected facilities, such an extension would do little to reduce the burden on small entities and would only result in a delay in the protection of workers provided by compliance with the proposed rule. OSHA solicits comment on the effects of extending phase-in dates for the other proposed requirements, particularly those for respirators, for small entities.

After considering all of the above alternatives and adopting those that were consistent with the mandate imposed by the OSH Act, OSHA has developed a proposed rule that will minimize the burden on affected employers, while maintaining the necessary level of worker protection.

OSHA's Response to SBREFA Panel Recommendations

Table VII–7 lists the SBREFA Panel Recommendations and OSHA's response to these recommendations. The complete SBREFA Panel Report is available for comment in the record as Exhibit 12 of Docket H–371.

TABLE VII–7.—OSHA'S RESPONSES TO SBREFA PANEL RECOMMENDATIONS

Panel recommendation	OSHA response
OSHA should define the terms ''establishment,'' ''firm'' and ''facility'' in the IRFA.	These terms are now defined in Chapter VI of the PEA.
OSHA should consider analyzing additional size classes of firms	OSHA now uses the SBA definitions of small entities and also analyzes entities with fewer than 20 employees in the IRFA.
OSHA should clarify and more carefully explain the requirements and engage in extensive outreach efforts to assure that the regulated community understands the regulation.	OSHA has provided tables illustrating requirements for groups of affected firms, added many clarifications to the Preamble and regulatory text, and plans extensive outreach upon publication of the final standard (see Preamble Section IX).

TABLE VII–7.—OSHA'S RESPONSES TO SBREFA PANEL RECOMMENDATIONS—Continued

Panel recommendation	OSHA response
OSHA should reexamine the definition of a suspect case and/or reexamine its approach to homeless shelters.	OSHA will conduct a special study of homeless shelters. This study is discussed in the IRFA. OSHA will also designate certain hearing dates for persons who wish to testify on homeless shelter issues.
OSHA should reconsider applying the standard to substance abuse centers.	OSHA has explained in the IRFA why it thinks that its treatment of substance abuse treatment centers is feasible and has solicited comment on this issue in the Issues Section of the Preamble.
OSHA should more carefully address the economic impacts on facilities that rely on Medicaid/Medicare or charitable funding.	OSHA has added a discussion of this issue to Chapter VI of the PEA.
OSHA's preamble and IRFA should explain OSHA's role and authority as compared to other voluntary and regulatory organizations; preamble should explain ongoing cooperative efforts; solicit comments on conflicts and ways of better coordinating with other organizations.	OSHA has added a preamble discussion of why OSHA regulates occupational exposure to TB, why other organizations are unable to do so effectively, and how OSHA has worked with other organizations. OSHA solicits comments on possible conflicts and better methods of coordination.
OSHA should examine additional alternatives, such as revising the proposed standard for greater consistency with CDC guidelines.	OSHA has added a discussion of additional alternatives suggested by SBREFA Panel members to the IRFA and has solicited comment on these alternatives in the Preamble.
OSHA should clarify that employers would only be required by the standard to determine the TB status of their county once per year, rather than monthly.	OSHA has clarified this issue in the Preamble.
OSHA should reexamine the standard and the economic analysis to ensure that the issues of part-time, multi-employer, and off-site workers have been adequately addressed. OSHA should also specifically address the issue of portability of training. OSHA should clarify the term ''accessibility'' in the context of employers with off-site employees.	OSHA has modified the standard to allow portability of non-site specific elements of training and to allow portability of skin tests. For off-site workers, OSHA has clarified in the Preamble that the standard may be made available at the primary workplace facility, provided there is a mechanism for immediate availability of information during the workshift.
OSHA should clarify exactly what is required for temporary AFB isolation.	The Summary and Explanation Section of the Preamble describes temporary AFB isolation, and OSHA's assumptions concerning the costs of such units are given in Chapter V of the PEA.
OSHA should clarify that engineering control provisions do not apply to home health care.	OSHA has clarified the point in Section IX of the Preamble.
OSHA should explain the differences in protection provided by surgical masks and respirators.	OSHA has explained this difference in Section IX of the Preamble.
OSHA should explain the reasons for its detailed respiratory protection program, why it considers manufacturers' instruction inadequate as a substitute for a respirator program, and why annual respirator program evaluation is necessary.	OSHA has discussed this issue in the Summary and Explanation Section of the Preamble.
OSHA should explain its intent to fold many aspects of respiratory protection provisions for occupational exposure to TB into the upcoming respirator standard.	OSHA has discussed this issue in the Summary and Explanation Section of the Preamble.
OSHA should explain the number of employees required to have medical surveillance in homeless shelters, the elements of a written medical opinion, and the importance of two-step skin testing.	OSHA provides an estimate of the number of employees requiring medical surveillance in Chapter V of the PEA. The regulation lists the elements of a medical opinion. The Preamble explains the importance of two-step skin testing.
OSHA should explain its basis for believing that two-step skin testing is appropriate for employees who have had BCG vaccinations.	OSHA has discussed this issue in the Summary and Explanation Section of the Preamble.
OSHA should clarify the interaction of workers' compensation and medical removal protection and examine more carefully the costs and impacts of medical removal protection on small firms that actually have an employee with a serious and costly active case of TB.	OSHA has addressed this interaction in both the Preamble and the IRFA, and has provided a special discussion in Chapter VI of the PEA on the economic impacts of the medical removal protection provision on small firms. OSHA has solicited comment on this issue.
OSHA should examine the potential cost savings associated with a provision that allows training to be ''portable'' (assuming the training is equivalent to that required by the standard). OSHA should clarify that posting a copy of the standard will be considered an adequate means of providing employees with the standard. OSHA should clarify its performance-oriented interpretations of the training requirements in the Preamble, and OSHA should examine the need for annual retraining for all employees.	OSHA has modified the proposed regulation to allow portability of non-site specific training and to allow employers to demonstrate employee competence rather than provide annual retraining. OSHA has clarified in the Preamble that posting a copy of the standard will be considered an adequate means of providing employees with the standard. OSHA has clarified in the preamble that the training is performance oriented and need not include training in topics not relevant to an employee's duties.
OSHA should clarify how the identification, referral, and notification requirements of the proposed standard can be met without breaching federal and state confidentiality regulations and statutes.	OSHA has added a discussion of this issue to the IRFA and the Preamble.
OSHA should include a discussion of the interaction between medical removal protection provisions and the Americans with Disabilities Act and the Family and Medical Leave Act.	OSHA has added a discussion of this issue to the IRFA and the preamble.
OSHA should solicit comment and request data on industry turnover rates in the Summary of the Preliminary Economic Analysis in the Preamble.	OSHA has solicited comment on this issue.
OSHA should reexamine its estimate of the number of hospices and adopt the most accurate figure.	OSHA has reexamined the issue of the number of hospices and retained its original estimate. OSHA has clarified that this estimate includes only free-standing hospices. Hospices that are parts of nursing homes and hospitals are included in estimates for those sectors.

TABLE VII–7.—OSHA'S RESPONSES TO SBREFA PANEL RECOMMENDATIONS—Continued

Panel recommendation	OSHA response
OSHA should clarify why family practice physicians were not included in the analysis, and solicit comment on the extent to which family practitioners conduct the kind of hazardous procedures that would place them within the scope of the rule.	OSHA has added physicians who conduct high hazard procedures to its economic analysis and has sought comment on whether family practitioners commonly conduct such procedures.
OSHA should consider estimating the effects of the rule on volunteers and should include a discussion explaining that the proposed rule does not apply to volunteers, although some states may choose to apply it to these categories of individuals.	OSHA has explained in the Preamble that the standard does not apply to bona fide volunteers. OSHA has solicited comments on states or localities that elect to extend OSHA requirements to volunteers and on the number of affected volunteers. OSHA will further examine the issue of the number of potentially affected volunteers in homeless shelters in its homeless shelter study.
OSHA should solicit comment on the number of small government jurisdictions affected by the draft proposed standard.	OSHA has solicited comments on this issue in the Preamble.
OSHA should include a discussion of tribal governments in its analysis and solicit comment on this issue.	OSHA has provided an estimate of the number of affected tribal facilities and has sought comment from tribal governments in the Preamble.
OSHA should remind small entities that OSHA's risk assessment will be part of the public record and is subject to comment, and that small entities may submit any appropriate additional literature or studies that OSHA should consider in determining the risk of occupational TB.	OSHA has solicited comments on several specific aspects of the risk assessment and benefits analysis, and on these analyses as a whole.
OSHA should discuss the annualization of costs in greater detail in the economic analysis.	Chapter V of the PEA and the summary of the PEA in the Preamble now discuss the annualization of costs.
OSHA should clarify its position on the costs and durability of various respirators that can be used to comply with the standard, and should seek additional comment on the costs and durability of respirators.	OSHA has reanalyzed the costs of respirators in hospitals, and has added a discussion of the uncertainties concerning the costs and durability of respirators to the PEA. OSHA has solicited comments on these issues in the Preamble.
OSHA should perform further analyses to identify the marginal costs of medical removal protection above and beyond worker compensation, should further assess the probability that employers will actually incur costs for medical removal protection if they have an employee with an active case of TB, and should incorporate the results of this reexamination into its determination of feasibility.	OSHA specifically addresses this issue in Chapter VI of the PEA and has sought comment on this issue.
OSHA should reassess whether affected facilities have reasonable access to facilities with AFB isolation rooms, solicit comments on this issue, and incorporate the results of this reexamination into its determination of feasibility.	OSHA has further examined this issue, and found that affected facilities do have reasonable access to AFB isolation rooms; however, OSHA is seeking comments on whether some affected facilities may not have adequate local access to facilities with AFB isolation.
OSHA should reexamine its analysis of the economic impacts of the proposed rule on firms, such as emergency medical services firms, that operate under the constraint of being unable to charge some of their clients.	OSHA has discussed this issue in Chapter VI of the PEA.

VIII. Unfunded Mandates Analysis

The proposed TB standard has been reviewed in accordance with the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1501 *et seq.*) and Executive Order 12875. OSHA estimates that compliance with the proposed standard will require expenditures of more than $100 million each year by employers in the private sector. Therefore, the proposed TB standard establishes a federal private sector mandate and is a significant regulatory action within the meaning of Section 202 of UMRA (2 U.S.C. 1532). OSHA has included this statement to address the anticipated effects of the proposed TB standard pursuant to Section 202.

OSHA standards do not apply to state and local governments except in states that have voluntarily elected to adopt an OSHA State Plan. Consequently, the proposed TB standard does not meet the definition of a ''federal intergovernmental mandate'' (Section 421(5) of UMRA (2 USC 658 (5)). In sum, the proposed TB standard does not impose unfunded mandates on state, local, and tribal governments.

The remainder of this section summarizes OSHA's findings as required by Section 202 of UMRA (2 U.S.C. 1532):

This standard is proposed under Section 6(b) of the OSH Act. The proposed standard has annualized costs estimated at $245 million and would save an estimated 138 to 190 lives per year as a result of TB infections avoided. An estimated 1,772 to 2,442 active TB cases will be averted annually as a result of the proposed rule. Compliance will also result in an estimated 24,333 to 32,719 infections averted. The proposed standard will impose no more than minimal costs on state, local or tribal governments. OSHA pays 50 percent of State plan costs but does not provide funding for state, local or tribal governments to comply with its rules.

OSHA does not anticipate any disproportionate budgetary effects upon any particular region of the nation or particular state, local, or tribal governments, or urban or rural or other types of communities. Chapters V and VI of the economic analysis provide detailed analyses of the costs and impacts of the proposed standard on particular segments of the private sector. OSHA has analyzed the economic impacts of the standard on the affected industries and found that compliance costs are, on average, only 0.18 percent of sales, and that few, if any, facility closures or job losses are anticipated in the affected industries. As a result, impacts on the national economy would be too small to be measurable by economic models. OSHA requests information on state and local government issues.

Pursuant to Section 205 of the UMRA (2 U.S.C. 1535), and having considered a variety of alternatives outlined in the Preamble and in the Regulatory Flexibility Analysis above, the Agency preliminarily concludes that the

proposed rule is the most cost-effective alternative for implementation of OSHA's statutory objective of reducing significant risk among employees to the extent feasible. OSHA solicits comment on these issues.

IX. Environmental Impacts

The provisions of this proposed standard have been reviewed in accordance with the requirements of the National Environmental Policy Act (NEPA) of 1969 [42 U.S.C. 432, *et seq.*], the Council on Environmental Quality (CEQ) NEPA regulations [40 CFR Part 1500], and OSHA's DOL NEPA Procedures [29 CFR Part 11]. As a result of this review, OSHA has preliminarily determined that this proposed standard will have no significant effect on air, water, or soil quality, plant or animal life, use of land, or other aspects of the environment.

X. Summary and Explanation of the Standard

Based on currently available data in the record, OSHA has preliminarily concluded that the requirements set forth in this proposed standard are those that are necessary and appropriate to provide adequate protection to employees exposed to tuberculosis (TB). In the development of this proposed standard, OSHA has carefully considered the numerous reference works, journal articles, and other data collected by OSHA since the initiation of this proceeding. In particular, OSHA has carefully considered the recommendations given in the document, ''Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-Care Facilities'' published by the Centers for Disease Control and Prevention beginning on page 54242 in the **Federal Register** of October 28, 1994 (Ex. 4B). OSHA also held a series of informal stakeholder meetings during the development of the proposal and considered the major points raised by the stakeholders during these meetings (Ex. 10). In addition, the proposal has undergone the Panel review process required by the Small Business Regulatory Enforcement Fairness Act (SBREFA)(5 U.S.C. Chapter 8) (Exs. 11 and 12). All of the information developed to assist the small entity representatives involved in the SBREFA panel process, the comments of these representatives, and the Panel's findings and recommendations to OSHA have been placed in the rulemaking record (Exs. 11 and 12).

Upon publication of the final standard, the Agency will undertake a number of compliance assistance activities that will be particularly beneficial to small entities. Past compliance assistance activities have included: publication of booklets summarizing the provisions of the standard; development of a compliance directive that answers compliance-related questions about the standard; development of compliance guides directed at assisting small businesses in complying with the standard; designation of certain OSHA employees in each Regional office with the responsibility of answering questions from the public about the standard; development of training materials; and provision of speakers and information for meetings and workshops of affected parties (particularly small business entities). OSHA anticipates initiating similar activities upon publication of the final standard for occupational exposure to tuberculosis.

Paragraph (a) Scope

Tuberculosis is a well-recognized occupational hazard (Ex. 4B). As discussed in the Health Effects section above, there are numerous epidemiological studies, case reports, and outbreak investigations that provide evidence to show that employees who are exposed to aerosolized *M. tuberculosis* have become infected with TB and in some cases have developed active TB disease. Of particular concern is the emergence of strains of multidrug-resistant TB. MDR–TB presents an additional hazard because individuals with MDR–TB may be infectious for weeks or months until an effective drug regimen can be successfully implemented and the patient rendered noninfectious. This in turn increases the likelihood that employees who must provide health care or other services to these individuals will be exposed. The risk of death from infections with MDR–TB is markedly increased. Outbreaks involving strains of MDR–TB have had mortality rates as high as 75% with death occurring 4 to 16 weeks after the diagnosis of disease (Ex. 3–38A).

Most of the TB outbreaks investigated occurred in large metropolitan areas. However, a recent study has shown that MDR–TB spread from New York City to patients in Florida and Nevada and health care workers in Atlanta, Georgia and Miami, Florida and to staff and patients in a nursing home in Denver, Colorado (Ex. 7–259). In addition, a growing percentage of TB cases are occurring among the foreign born. CDC reported that in 1995 the number and proportion of cases among the foreign-born had increased 63% since 1986 (Ex. 6–34). These two pieces of information taken together clearly illustrate the relationship between population mobility and the spread of TB disease. Thus, TB is a nationwide problem. Although the total number of cases declined to its pre-1985 levels after a resurgence from 1985 to 1994, the rate of active TB cases reported in 1995 (i.e., 8.7/100,000) is still two and one half times greater than the target rate of 3.5 active cases per 100,000 population for the year 2000 proposed by the Advisory Committee on the Elimination of Tuberculosis (Ex. 6–19). In addition, there is substantial variability from year to year in the increases and decreases in the number of cases reported by each state. In 1995, all fifty states reported cases of TB, and fifteen of these reported increases over 1994 (Ex. 6–34). At the county level, approximately 57% of counties in the U.S. reported one or more cases of active TB, with 17% of the counties in the U.S. reporting 5 or more cases (Ex. 7–262). In addition, approximately 91% of the U.S. population resides in the counties that reported one or more cases of active TB. Thus, while 43% of the counties in the U.S. reported no cases of active TB, 10% of the U.S. population resides in those counties. The nationwide prevalence of TB infection in the U.S. population in 1994 (age 18 years an older) is approximately 6.5 percent.

The recent resurgences in the number of reported cases of active TB have brought to attention a number of problems in existing TB control plans. The problem is most apparent in health care facilities such as hospitals, but it also extends to other work settings where the population served is at increased risk for tuberculosis, such as shelters for the homeless, correctional institutions and settings where high-hazard procedures are performed.

There are a number of factors that make occupational exposure to tuberculosis an important concern at the present time. One factor is that the results from OSHA's quantitative risk assessment show a high potential for TB infection for employees who work in close proximity to individuals with infectious TB. A second factor is that the cases of tuberculosis are not distributed evenly throughout the entire population. There is a relatively high prevalence of tuberculosis infection and disease in certain populations, such as residents of nursing homes and inmates of correctional institutions. A third factor is the rise of MDR-TB. These factors increase the risk for workers who have occupational exposure. Occupational exposure occurs through contact with air that may contain aerosolized *M. tuberculosis* as a result of the performance of an employee's

duties. Most often this occurs when an employee is working in the same environment with an individual with infectious TB. It could also occur when repairing air systems that may be carrying aerosolized *M. tuberculosis.*

Individuals with infectious tuberculosis expel airborne particles called droplet nuclei when they cough, sneeze, or speak. These droplet nuclei contain the organism that causes tuberculosis, *M. tuberculosis.* Normal air currents can keep these droplet nuclei airborne for long periods of time and spread them throughout a building (Ex. 5–5). When employees breathe the air that contains *M. tuberculosis,* they are at risk for TB infection which may result in illness and, in some cases, death. Employees also may be exposed when laboratory procedures produce aerosols of *M. tuberculosis.* There is an extensive discussion of the scientific literature related to occupational transmission in Section IV, Health Effects, which will not be repeated here.

Because the CDC does not consider fomites, e.g., objects such as clothing or silverware, to present a hazard for transmission of *M. tuberculosis,* this standard is designed to eliminate or reduce airborne exposures only. Even though it is well established that exposure to TB contaminated air is the route of exposure related to the development of disease, it is not known what levels of contamination in the air cause the disease. Unlike toxic chemicals, a Permissible Exposure Limit (PEL) for air concentration of TB cannot be determined. As described in the Health Effects section of this preamble, it is known that a number of factors contribute to the probability of infection. For example, exposures of relatively short duration, such as a day or two, can result in infection of the employee. OSHA has used these findings to show that certain types of work, in certain industries, can result in significant risk of TB infection. For these reasons, OSHA is defining the scope of the standard by listing the locations and services where this proposed standard would apply. Employers with employees working at those locations, and employers whose employees provide the listed services, are covered by the standard. The proposed standard applies to occupational exposures to tuberculosis that occur in certain specified workplaces, such as a hospital, or as the result of providing services, such as emergency medical treatment. Paragraphs (a)(1) through (10) of the proposal describe the various work settings and services that are covered under the scope of the standard.

Paragraph (a)(1) states that the standard applies to occupational exposure to TB occurring in hospitals. The record contains many examples of occupational exposures with resultant TB infection and disease that have occurred in hospitals (e.g., Exs. 5–11; 5–15; 7–43; 7–45). Recent outbreaks involving multidrug-resistant strains of *M. tuberculosis* have compounded the long recognized risk of TB in such settings.

Hospitals not only provide medical care for persons with diagnosed tuberculosis, they also provide medical care for individuals who may be at increased risk for TB. For example, hospitals provide isolation for individuals with suspected or confirmed infectious TB and contain rooms or areas where high-hazard procedures on individuals with infectious TB are performed that place employees at risk of exposure. In addition, the client population encountered in hospitals is generally at higher risk of developing active TB. Individuals with HIV disease, for example, are at increased risk for developing disease when they have been infected with *M. tuberculosis.* In addition, medically underserved populations with an increased prevalence of tuberculosis (e.g., homeless persons) may seek acute care in the emergency rooms of hospitals.

Employees who are at risk for occupational exposure and potential infection and disease include all employees who have direct contact with persons with infectious tuberculosis. These may include but are not limited to physicians, nurses, aides, dental workers, medical technicians, workers in laboratories and autopsy suites, and emergency medical service personnel (Ex. 4B). They may also include persons not involved in direct patient care but who have occupational exposure as a result of providing other services such as dietary, housekeeping, and maintenance staff.

Paragraph (a)(2) covers occupational exposure occurring in long-term care facilities for the elderly. Persons aged 65 and older constitute a large repository of *M. tuberculosis* infection in the United States (Ex. 6–14). Many of these individuals were infected many decades ago when TB was a much more common disease. Some of the TB occurring in this age group arises from preexisting infection of long duration and other cases may be the result of recent infections. In addition, elderly persons residing in nursing homes are at greater risk than elderly persons living in the community. In its 1990 guidelines, ''Prevention and Control of Tuberculosis in Facilities Providing Long-term Care to the Elderly,'' the CDC cited 1984–1985 data indicating a TB case rate of 39.2 per 100,000 population, a rate that was twice that of elderly persons living in the community (Ex. 6–14). The same document stated that CDC had found that the increased risk for nursing home employees was three times higher than the rate expected for employed adults of similar age, race, and sex. Examples of employees in long-term care facilities who may have occupational exposure include, but are not limited to, registered nurses, licensed practical nurses, nursing assistants, and auxiliary personnel. OSHA has not included other long-term care facilities under the scope of the standard. The Agency requests comment and supporting data on whether it is appropriate to expand the scope of the standard to include other long-term care facilities that may provide health care or other services to individuals who may be at an increased risk of developing infectious TB, thereby presenting a potential source of exposure to employees working in those facilities. An example of another long-term care facility is a psychiatric hospital.

Paragraph (a)(3) covers occupational exposure occurring in correctional facilities and other facilities that house inmates or detainees. Facilities such as prisons, jails and detainment centers operated by the Immigration and Naturalization Service (INS) would be included in the scope of the standard. The CDC considers TB to be a ''major'' problem in correctional institutions, with cases occurring at a frequency three times that of the general population (Ex. 7–25). In addition to a number of outbreaks that have occurred, the overall incidence of tuberculosis in the prison population is increasing. This can be attributed to, (1) the over-representation of populations at high risk for TB in prisons and jails, and (2) environmental factors that promote the transmission of TB. Compared to the general population, inmates have a higher prevalence of TB infection. The population of correctional facilities is also characterized as having a high prevalence of individuals with HIV infection and intravenous drug users, factors that place these inmates at a higher risk of developing active TB. In addition, many prisons and jails are old, overcrowded, and have inadequate ventilation. Inmates may be moved frequently within a facility and between facilities, increasing the number of persons, both inmates and employees, exposed to an infected individual and making contact tracing difficult.

Medical records and treatment information may not follow the inmate in a timely manner, which may, in turn, lead to inadequate drug therapy.

Detention facilities, such as those operated by the INS, may house persons who are entering this country from countries with a prevalence of TB many times that of the U.S. population (Ex. 6–26). In addition, there may be a substantial number of individuals in these facilities currently awaiting deportation who have an additional increased risk of TB because they have been previously incarcerated in correctional institutions. In 1995, CDC reported that approximately 36% of the total reported cases of active TB were among the foreign-born (Ex. 6–34). This marks a 63% increase since 1986. In addition, among those persons whose records contained information on date of arrival to the U.S., approximately 30% developed active TB within one year of entering the country and approximately 53% developed active TB within 5 years of entering the country. Employees who may have occupational exposure in these facilities include, but are not limited to, correctional officers, physicians, dentists, nurses, and other health care workers.

Paragraph (a)(4) covers occupational exposure occurring in hospices. CDC identified hospices as one of the inpatient health care facilities to which its 1994 TB guidelines apply. CDC's Guidelines recommend that individuals with suspected or confirmed infectious TB be managed in the same manner using similar methods of infection control as recommended for hospitals. Hospices serve the same high-risk populations that hospitals serve. In addition, individuals receiving hospice care may be at increased risk for tuberculosis if they are members of a high risk group, which includes groups whose members have a medical condition that increases the likelihood of developing active tuberculosis (e.g., HIV disease, end stage renal disease, certain carcinomas). Employees who may have occupational exposure include, but are not limited to, physicians, nurses, aides, social workers, and other health care workers.

Occupational exposure occurring in shelters for the homeless is covered under paragraph (a)(5). Residents of shelters for the homeless comprise a population that is also at increased risk for tuberculosis. Members of this population are more likely to have risk factors that are associated with TB than the general population although the exact prevalence of TB in this population is unknown. The data quoted in CDC's 1992 document ''Prevention and Control of Tuberculosis Among Homeless Persons'' indicated a prevalence of clinically active tuberculosis among homeless adults ranging from 1.6% to 6.8% (Ex. 6–15). The prevalence of latent tuberculosis ranged from 18% to 51% and there was a point prevalence of active TB of 968 cases/100,000 homeless adults (Ex. 6–15). Similar to the population in correctional facilities, residents of homeless shelters have a high prevalence of HIV infection and intravenous drug use, factors that increase the likelihood that their infections will progress to active TB. In addition, environmental factors such as overcrowding and poor ventilation promote the transmission of disease. Examples of employees who may have occupational exposure include, but are not limited to, intake workers and health care workers who have contact with residents of homeless shelters.

Paragraph (a)(6) covers occupational exposure occurring in facilities that provide treatment for drug abuse. Based on tuberculin skin testing reported in 1993, 13.3% of the clients of drug treatment facilities had evidence of TB infection (Ex.6–8). Many of these persons have a history of intravenous-drug use and either have or are at risk for HIV infection. These persons are at increased risk for developing active TB and transmitting the disease to others. Many of these individuals may discontinue treatment prematurely even if they are diagnosed and started on effective drug treatment. In addition, the CDC reported that studies in some areas have shown that over 20% of selected inner city intravenous drug user populations have tuberculous infection (Ex. 3–37). The CDC thus concluded that drug center clients and staff are at risk of becoming infected. Employees in drug treatment facilities who may have occupational exposure include, but are not limited to, counselors, nurses, physicians and other staff.

Work settings where occupational exposure occurs as a result of the performance of high-hazard procedures, which, for the purposes of this standard, are certain procedures performed on individuals with suspected or confirmed infectious TB, are also covered under the scope of the standard as stated under paragraph (a)(7). High-hazard procedures are procedures that are cough-inducing or aerosol-generating that are likely to result in droplet nuclei being expelled into the air. A definition and discussion of high-hazard procedures can be found under paragraph (j), Definitions, of this Summary and Explanation. Health care workers and other employees who are either performing or assisting with these procedures or are in the general vicinity are at an increased risk of inhaling droplet nuclei and therefore have occupational exposure. The 1994 CDC guidelines recommend in Section G, ''Cough-Inducing and Aerosol-Generating Procedures'' that special precautions be taken when these procedures are performed (Ex. 4B). Health care workers, such as physicians, nurses, technicians and others who perform or assist in the performance of high-hazard procedures have occupational exposure. Other employees who may be in the room or area when such procedures are performed would be expected to have occupational exposure as well.

Paragraph (a)(8) applies to occupational exposure that occurs in laboratories that handle specimens that may contain *M. tuberculosis,* process or maintain those specimens or the resulting cultures, or perform any related activity that may result in the aerosolization of *M. tuberculosis. M. tuberculosis* is a proven hazard to laboratory personnel (Exs. 7–68, 7–72, 7–142, 7–143). Aerosols present the greatest hazard in laboratories. Tubercle bacilli may be present in sputum, gastric lavage fluids, cerebrospinal fluid, urine, and in lesions from a variety of tissues. In addition, the bacilli are grown in culture to increase their concentration beyond what would normally be found in the sample for purposes of identification and susceptibility testing. The bacilli may survive in heat-fixed smears and may be aerosolized in the preparation of frozen sections and during manipulation of liquid cultures. CDC/NIH's manual ''Biosafety in Microbiological and Biomedical Laboratories'' recommends Biosafety Level 2 or 3 for such laboratories depending on the procedures being performed (Ex. 7–72). Employees who may have occupational exposure include a wide variety of laboratorians. Examples include, but are not limited to, medical technologists, laboratory technicians, physicians, and research scientists.

Occupational exposure incurred by temporary or contract employees is also covered under the Scope to the extent that the occupational exposure occurs in one of the work settings listed under paragraphs (a)(1) through (a)(8). For example, if a nurse working for a temporary employment service were hired by a hospital to work on a TB ward, that temporary nurse would be covered under the scope of the standard. Physicians who are employees (e.g., of an independent corporation) yet who

practice and are exposed in a covered facility, such as a hospital, are also covered by the standard. Similarly, in any of the work settings listed under paragraph (a)(1), temporary or contract personnel who incur occupational exposure to TB as a result of their temporary or contract work would be covered by the standard. The occupational exposure experienced by these employees would be expected to be similar to that of other employees performing the same tasks and procedures in the work setting that has contracted for their services. A note has been added to the proposed standard to make clear that these types of employees are covered under the scope.

This note also clarifies that repair, replacement, or maintenance personnel, working in any of the work settings covered under paragraphs (a)(1) through (a)(8), who service air systems or equipment or who renovate, repair or maintain areas of buildings that may reasonably be anticipated to contain aerosolized *M. tuberculosis* are also covered under the scope of the standard. The standard requires the use of engineering controls, such as isolation rooms, to reduce the concentration of droplet nuclei and therefore reduce the likelihood of TB infection and subsequent illness. The ventilation systems that exhaust air from isolation rooms may reasonably be anticipated to contain aerosolized *M. tuberculosis.* Maintenance and other workers who are responsible for the servicing and repair of ventilation systems that handle air that may contain aerosolized *M. tuberculosis* are at risk for occupational exposure when, as the result of performing their duties, they are exposed to TB contaminated air moving through the ventilation system. Examples of employees who may have occupational exposure include heating, ventilation, and air conditioning (HVAC) maintenance personnel.

In addition, there may be employees who are responsible for renovating, repairing, or maintaining areas of buildings where exposure to aerosolized *M. tuberculosis* may occur other than those associated with the ventilation systems. Maintenance staff who need to repair fixtures in an isolation room, or contractor personnel hired to provide housekeeping in isolation rooms or areas, are examples of such employees who would also be covered under the standard. OSHA expects that such exposures would occur only rarely. In many circumstances, minor non-emergency maintenance activities could be performed by health care personnel required to enter the isolation rooms or areas for other reasons, such as to care for a patient. However, there may be activities that necessitate the expertise of certain maintenance employees which could place those employees at risk of occupational exposure. Those employees would therefore be covered under the scope of the standard.

Paragraph (a)(9) applies to occupational exposure occurring during the provision of social work, social welfare services, teaching, law enforcement or legal services, where the services are provided in the facilities included in paragraphs (a)(1) through (a)(8), or in residences, to individuals who are in AFB isolation, or are segregated or otherwise confined due to having suspected or confirmed infectious tuberculosis. This paragraph is intended to cover those types of employees who must provide services to individuals who have been identified beforehand as having suspected or confirmed infectious tuberculosis and who have either been isolated or segregated in isolation rooms or areas or have been confined in their homes. For example, certain social workers may need to enter AFB isolation rooms or areas or visit homes of people who have suspected or confirmed infectious tuberculosis for the purposes of collecting information or providing discharge planning. While OSHA believes that it would be preferable to collect such information over the telephone in order to prevent occupational exposure, the Agency realizes that there may be situations where direct contact with these isolated or confined individuals may be necessary. In these limited situations, these employees would be covered under the scope of the standard. There may also be situations where teachers may be providing tutoring to individuals isolated with suspected or confirmed infectious tuberculosis. Again, OSHA believes that such situations would be limited and that most educational instruction could be delayed until an individual was determined to be noninfectious. However, where teachers must provide instruction to individuals identified as having suspected or confirmed infectious TB, those teachers would be covered under the scope of the standard. In addition, certain law enforcement officers might have to be in contact with individuals who have been identified as having suspected or confirmed infectious tuberculosis. For example, they may have to transfer such an individual from a correctional or detainment facility to a hospital for diagnosis or treatment. Because these workers must be in direct contact with the individual during transport, perhaps for long periods of time and probably in an enclosed vehicle, such employees could incur significant occupational exposure. Paragraph (a)(9) would assure that such employees would be covered under the standard. Similarly, there may be occasions where attorneys must consult with clients or inmates who have been isolated or segregated because they have been identified as having suspected or confirmed infectious tuberculosis. Such attorneys would be covered under the standard in the limited situations where these consultations cannot be done by phone or delayed until the individual has been determined to be noninfectious. Under paragraph (a)(9), OSHA has specified certain employee groups that it believes would have to enter AFB isolation rooms or areas or homes where individuals are confined due to suspected or confirmed infectious TB, in order to provide services which may result in occupational exposure. OSHA requests comments and data as to whether there are other employee groups that may incur occupational exposure and thus need protection under this paragraph.

Paragraph (a)(10) applies to occupational exposure occurring during the provision of emergency medical services, home health care, and home-based hospice care. Emergency medical service employees may provide emergency treatment and transportation for individuals with suspected or confirmed tuberculosis. For example, in addition to serving the same high-risk client population as hospitals, emergency medical services are often used to transport individuals who have been identified as having either suspected or confirmed infectious tuberculosis from a facility with inadequate isolation capabilities to another facility better equipped to isolate these individuals. Proximity to the patient and time spent within an ambulance or other emergency vehicle affects the likelihood of occupational exposure as the result of breathing droplet nuclei generated when the patient coughs or speaks. Examples of employees who may have occupational exposure include but are not limited to emergency medical technicians, paramedics, and, in some localities, fire fighters.

The 1994 CDC guidelines identify health care workers who provide medical services in the homes of patients with suspected or confirmed infectious tuberculosis as being at risk and recommend precautions to be used in these settings (Ex. 4B). Employees who provide home-based care serve a

client population similar to that of hospitals (e.g., individuals who may be immunocompromised). Employees such as nurses and aides who provide care to these individuals would be expected to have occupational exposure.

OSHA is also proposing that certain limited construction activities be included under the scope of the standard; however, the Agency believes that the proposed standard would have little impact on this sector. The standard would apply to construction operations occurring in the work settings covered by the scope of the standard where there is a reasonable anticipation of exposure to aerosolized *M. tuberculosis,* e.g., while rebuilding an HVAC system that would connect to an existing one that is in use. The standard is not intended to cover employees involved in other construction operations where they would not have occupational exposure to air which may reasonably be anticipated to contain aerosolized *M. tuberculosis* (e.g., a crane operator constructing a new wing of a hospital). The standard would apply only to construction employees who would incur occupational exposure to tuberculosis. Such a case might arise during maintenance operations on an air system that carries air that may reasonably be anticipated to contain aerosolized *M. tuberculosis* or during renovation, repair, or alteration of areas of buildings that may reasonably be anticipated to contain aerosolized *M. tuberculosis.* The probability of exposure to *M. tuberculosis* during these activities may be high and it is necessary, therefore, for employees performing the work to wear respirators, receive medical surveillance and be protected by the other provisions of the proposed TB standard. Employees of such contractors are subject to the same levels of TB exposure and need the same protection as other exposed employees. Therefore, OSHA proposes to cover these employees under the TB standard and has included construction within the standard's scope.

Thus, although the impact of the standard will be limited, OSHA believes that construction should not be exempted from the proposed standard. OSHA believes that a loophole would be opened in the enforcement of the standard if construction were exempted. The distinction between maintenance and construction is often an ambiguous one. If construction were excluded, contractors, such as HVAC contractors, might argue that their work is ''construction'' and that they are not covered by the standard. By covering construction, this ambiguity does not arise. This approach is consistent with that taken in other standards (e.g., Ethylene Oxide, 29 CFR 1910.1047; Benzene, 29 CFR 1910.1028).

Several of the sectors covered by the proposed standard may be utilizing volunteers for assistance in the workplace. Under the OSH Act, OSHA is mandated to protect employees against workplace hazards. Consequently, volunteers are not covered by OSHA standards because they are not employees. However, employers should be aware that simply labeling a person as a volunteer is not determinative of whether an employer/employee relationship exists, if the person is compensated for his or her services. Some states or localities may decide to extend the protections of OSHA standards to volunteers; however, such action is the independent decision of these jurisdictions and is not a requirement of the OSH Act.

In addition, the proposed standard applies in situations when an employer has part-time employees, or where employees of other employers are working in a covered facility. These employees are covered by the standard in the same manner as other employees who have occupational exposure to tuberculosis. For example, they would be provided with the same protections as full-time on-site employees, such as being included in the exposure determination, being trained, being provided with medical surveillance, and being issued respiratory protection if necessary. With regard to employers who provide employees to other employers (e.g., personnel providers, temporary help agencies, nurse registries), a shared responsibility for worker protection exists between the provider and the client or ''host'' employer. The safety and health rights of temporary or ''leased'' or contracted employees are the same as the rights of those who are employed directly by the host employer. The host employer is generally responsible for safety and health measures taken to address hazards that are an integral part of the workplace the host employer controls. Where other employers are involved, contractors or other ''providers,'' a joint employer-employee relationship may exist in which both (or more) employers share responsibility for the safety and health of the employees. OSHA's concern is to assure that workers receive full protection under this standard. Who provides which protections to the various employees may be specified as a matter of contract or employment agreement existing between the client/host and the contractor/provider. In a typical arrangement, for example, the provider employer might provide the generic training required by the standard and assure that proper follow-up medical evaluation occurs after an exposure incident. Host employers would typically control potential exposure conditions and fulfill other requirements of the standard, such as site-specific training and respiratory protection.

While the proposed standard covers a number of different work settings, as described above, OSHA recognizes that many different types of activities occur in these different settings. Thus, not all provisions of the proposed standard would apply in each work setting. The provisions that are required will vary to some degree, depending on the type of activities done in the work setting. In order to give employers guidance as to what provisions would be applicable in their work setting, OSHA has developed a series of charts of the requirements that are most likely to be applicable for the affected industries.

The following charts outline provisions that would be required for employers covered under the scope of the proposed TB standard. (*Employers who qualify for the limited program as outlined under Paragraph (b), Application, should consult Appendix A for applicable provisions.*) The charts are categorized either by the types of infection control activities that may be common among different work settings (e.g., early identification and transfer of individuals with suspected or confirmed infectious TB) or by a particular occupational work group (e.g., emergency medical services, home health care). These charts are designed to give employers a guide to the regulatory text by outlining the provisions of the proposed standard that are applicable for various types of work settings. These charts summarize the general responsibilities of a particular required provision. The regulatory text should be consulted for more specific details on particular provisions.

In addition, it should also be kept in mind that even though these charts are categorized by the type of activities occurring at a worksite, the categories do not necessarily always follow industry lines (i.e., an employer under a specific industry sector may not always fall under a particular category outlined in the following charts). The charts are not designed to serve as a stand alone check list for any one industry sector. Due to the varying activities that may take place in work settings encompassed by an industry sector, the charts may not account for every applicable provision in every work setting. The charts are intended to provide general guidance as to what

OSHA anticipates to be applicable provisions. Therefore, it is important that employers evaluate the types of activities occurring in settings where their employees work to determine which of the provisions of the proposed standard would be applicable. In order to give employers guidance, OSHA has listed some of the types of industry sectors that the Agency assumes are likely to fall under a particular category, given OSHA's current understanding of the activities commonly occurring in these work settings.

OSHA requests comments on these assumptions and on the charts, and particularly, on how the charts can be made more user friendly and be better organized to help serve as a guide for employers trying to comply with the standard. The following charts are included:

Chart 1: What Would Be Required in Work Settings Where Individuals with Suspected or Confirmed Infectious TB are Admitted or Provided Medical Services?

Chart 2: What Would Be Required in Work Settings Where Early Identification and Transfer Procedures are Used for Individuals with Suspected or Confirmed Infectious TB?

Chart 3: What Would Be Required for Employers with Employees Who Provide Services to Individuals Who Have Been Isolated or Otherwise Confined Due to Having Suspected or Confirmed Infectious TB or Who Work in Areas Where the Air Has Been Identified As Reasonably Anticipated to Contain Aerosolized *M. tuberculosis*?

Chart 4: What Would Be Required for Home Health Care and Home-Based Hospice Care?

Chart 5: What Would Be Required for Emergency Medical Services?

Chart 6: What Would Be Required for Clinical and Research Laboratories?

Chart 7: What Would Be Required for Personnel Services?

Chart 1: What Would Be Required in Work Settings Where Individuals with Suspected or Confirmed Infectious TB Are Admitted or Provided Medical Services?

OSHA anticipates that Hospitals will be the primary type of facility falling under this category. In general, individuals requiring isolation are transferred to hospitals that have isolation capabilities. In addition, medical services such as diagnostic testing for evaluating TB disease are performed in a hospital setting. This category also covers work settings where high-hazard procedures are performed, e.g., medical examiners' offices. (Laboratories are covered in a later chart). However, there may be other work settings such as correctional facilities or long-term care facilities for the elderly that provide isolation or perform high-hazard procedures on individuals with suspected or confirmed infectious TB. In these cases, employers at these facilities would be required to comply with the provisions outlined in this chart.

What Would Be Required in Work Settings Where Individuals With Suspected or Confirmed Infectious TB Are Admitted or Provided Medical Services?
(c) Exposure Control
(c)(1) Exposure Determination
(c)(2)(i) Written Exposure Control Plan including:
(A) the exposure determination
(B) procedures for providing information to occupationally exposed employees about individuals with suspected or confirmed infectious TB or air that may reasonably be anticipated to contain aerosolized *M. tuberculosis*
(C) procedures for reporting exposure incidents
(c)(2)(iii):
(A) procedures for prompt identification of individuals with suspected or confirmed infectious TB
(B) procedures for isolating and managing the care of individuals with suspected or confirmed infectious TB (e.g., minimizing the time and number of employees entering an isolation room)
(C) a list of high-hazard procedures
(D) a schedule for inspection, maintenance, and performance monitoring of engineering controls
(c)(2)(iv) If the employer operates an onsite laboratory, the plan must include a determination as to whether the facility should operate at Biosafety Level 2 or 3 containment and document the need for controlled access, anterooms, sealed windows, directional airflow, measures to prevent the recirculation of lab exhaust air, filtration of exhaust air and thimble exhaust connections.
(c)(2)(vi) Document the number of confirmed cases of TB if claiming reduced responsibilities under paragraph (g)(3)(iii)(D)
(c)(2)(vii) The exposure control plan must be:
(A) accessible
(B) reviewed annually and updated whenever necessary
(C) available for copying by the Assistant Secretary and Director upon request
(d) Work Practices and Engineering Controls
All provisions of paragraph (d) are applicable
(e) Clinical and Research Laboratories
If the facility operates an onsite laboratory, the additional provisions under paragraph (e) must be followed (See Chart 6 for Clinical and Research Laboratories)
(f) Respiratory Protection
(f)(1)(i) Provide respirators to employees who:
(A) enter isolation rooms or areas in use for TB isolation
(B) are present during the performance of procedures or services for an individual with suspected or confirmed infectious TB who is not masked
(C) transport an unmasked individual with suspected or confirmed infectious TB within the facility
(D) repair, replace, or maintain air systems or equipment that may reasonably be anticipated to contain aerosolized *M. tuberculosis*
(E) work in an area where an unmasked individual with suspected or confirmed infectious TB has been segregated or otherwise confined
(f)(1)(iii) Provide respirators at no cost and assure that the employee uses the respirator in accordance with this standard
(f)(1)(iv) Assure that the employee dons the respirator before entering any of the work settings or performing any of the tasks identified in paragraph (f)(1)(i) (A) through (E) and uses it until leaving the work setting or the task has been completed
All remaining provisions of paragraph (f) are applicable, i.e., (f)(2)–(f)(8)
(g) Medical Surveillance
All provisions of paragraph (g) are applicable
(h) Communication of Hazards and Training

What Would Be Required in Work Settings Where Individuals With Suspected or Confirmed Infectious TB Are Admitted or Provided Medical Services?
(h)(1)(i) Label air systems that may reasonably be anticipated to contain aerosolized *M. tuberculosis* ''Contaminated Air—Respiratory Protection Required''
(h)(1)(ii) If the employer operates an onsite laboratory, label clinical and research laboratory wastes with the biohazard symbol
(h)(2)(i) Post signs at entrances to:
(A) isolation rooms or areas
(B) areas where procedures or services are being performed on an individual with suspected or confirmed infectious TB
(C) clinical and research laboratories where *M. tuberculosis* is present if the employer operates an onsite laboratory
(h)(2)(ii) Ventilate isolation rooms or areas vacated by individuals with suspected or confirmed infectious TB, in accordance with Appendix C, unless those individuals are medically determined to be noninfectious
(h)(2)(iii) Signs must be readily visible and have a stop sign with the legend ''No Admittance Without Wearing a Type N95 or More Protective Respirator''
(h)(2)(iv) Signs at the entrances to clinical or research laboratories (for employers who operate onsite laboratories) and autopsy suites where procedures are being performed that may generate aerosolized *M. tuberculosis*
(h)(3) Information and Training
All elements are applicable
(i) Recordkeeping
All recordkeeping is applicable

Chart 2: What Would Be Required in Work Settings Where Early Identification and Transfer Procedures Are Used for Individuals With Suspected or Confirmed Infectious TB ?

OSHA anticipates that the types of establishments falling under this category are likely to be long term care facilities for the elderly, correctional facilities, immigration detainment facilities, hospices, homeless shelters, substance abuse treatment centers, and hospitals that do not admit individuals with suspected or confirmed infectious TB. In these work settings, employers will use the signs and symptoms of active TB as well as any other available information (e.g., tuberculin skin test status) to identify individuals with suspected or confirmed infectious TB. These individuals will then be transferred to facilities with appropriate isolation capabilities. Therefore, facilities that transfer do not need to have engineering controls. Temporary engineering controls will only be necessary in limited situations where transfer cannot be accomplished within 5 hours.

What Would Be Required in Work Settings Where Early Identification and Transfer Procedures Are Used for Individuals With Suspected or Confirmed Infectious TB?
(c) Exposure Control
(c)(1) Exposure Determination
(c)(2)(i) Written Exposure Control Plan including:
(A) the exposure determination
(B) procedures for providing information to occupationally exposed employees about individuals with suspected or confirmed infectious TB or air that may reasonably be anticipated to contain aerosolized *M. tuberculosis*
(C) procedures for reporting exposure incidents
(c)(2)(ii) Employers who transfer individuals with suspected or confirmed infectious TB must include in the plan: procedures for prompt identification, masking or segregation, and transfer of such individuals
(c)(2)(vi) Document the number of confirmed cases of TB if claiming reduced responsibilities under paragraph (g)(3)(iii)(D)
(c)(2)(vii) The exposure control plan must be:
(A) accessible
(B) reviewed annually and updated whenever necessary
(C) available for copying by the Assistant Secretary and Director upon request
(d) Work Practices and Engineering Controls
(d)(1) Use work practices and engineering controls to eliminate or minimize employee exposure to *M. tuberculosis*
(d)(2) Implement the work practices in the Exposure Control Plan
(d)(3) Identify individuals with suspected or confirmed infectious TB and:
(i) mask or segregate the individual until transfer can be accomplished
(ii) place the individual in temporary isolation if transfer cannot be accomplished within 5 hours from the time of identification
(d)(5) Engineering controls (i.e., negative pressure, direct exhaust or HEPA filtration, etc.) shall be used when temporary isolation is used
(d)(6) Provide information about TB hazards to any contractor who provides temporary or contract employees who will incur occupational exposure
(f) Respiratory Protection
(f)(1)(i) Provide respirators to employees who:
(A) enter a temporary isolation room or area
(E) work in an area where an unmasked individual with suspected or confirmed infectious TB has been segregated or otherwise confined and is awaiting transfer
(f)(1)(iii) Provide respirators at no cost and assure that the employee uses the respirator in accordance with this standard
(f)(1)(iv) Assure that the employee dons the respirator before entering the work setting and uses it until leaving the work setting
All remaining provisions of paragraph (f) are applicable, i.e., (f)(2)–(f)(8)
(g) Medical Surveillance
All provisions of paragraph (g) are applicable
(h) Communication of Hazards and Training
(h)(1)(i) Label air systems that may reasonably be anticipated to contain aerosolized *M. tuberculosis* ''Contaminated Air—Respiratory Protection Required'' if temporary isolation is used
(h)(2)(i)(A) Post signs at entrances to temporary isolation rooms or areas
(h)(2)(ii) Ventilate temporary isolation rooms or areas vacated by individuals with suspected or confirmed infectious TB in accordance with Appendix C, unless those individuals are medically determined to be noninfectious
(h)(2)(iii) Signs used for temporary isolation must be readily visible and have a stop sign with the legend ''No Admittance Without Wearing a Type N95 or More Protective Respirator''

What Would Be Required in Work Settings Where Early Identification and Transfer Procedures Are Used for Individuals With Suspected or Confirmed Infectious TB?
(h)(3) Information and Training All elements are applicable (i) Recordkeeping All recordkeeping is applicable

Chart 3: What Would Be Required for Employers With Employees Who Provide Services to Individuals Isolated or Otherwise Confined Due to Having Suspected or Confirmed Infectious TB or Who Work in Areas Identified as Reasonably Anticipated to Contain Aerosolized M. tuberculosis?

OSHA anticipates that the type of employees falling under this category will be workers providing social work services, social welfare services, teaching, law enforcement or legal services to individuals who are in isolation or confined to their homes due to having suspected or confirmed infectious TB. Also included in this category are maintenance employees such as contract HVAC maintenance employees who work on air systems that have been identified as carrying air that may reasonably be anticipated to contain aerosolized *M. tuberculosis*. Employers in these situations will not need to perform early identification procedures since the identification of individuals with suspected or confirmed infectious TB has already been accomplished. Similarly, air systems will already be labeled as containing ''Contaminated Air''.

What Would Be Required for Employers with Employees Who Provide Services to Individuals Isolated or Otherwise Confined Due to Having Suspected or Confirmed Infectious TB or Who Work in Areas Identified as Reasonably Anticipated to Contain Aerosolized *M. tuberculosis*?
(c) Exposure Control (c)(1) Exposure Determination (c)(2)(i) Written Exposure Control Plan including: (A) the exposure determination (B) procedures for providing information to occupationally exposed employees about individuals with suspected or confirmed infectious TB or air that may reasonably be anticipated to contain aerosolized *M. tuberculosis* (C) procedures for reporting exposure incidents (c)(2)(vii) The exposure control plan must be: (A) accessible (B) reviewed annually and updated whenever necessary (C) available for copying by the Assistant Secretary and Director upon request (d) Work Practices and Engineering Controls (d)(1) Use work practices to eliminate or minimize employee exposure to *M. tuberculosis* (d)(2) Implement the work practices in the Exposure Control Plan (d)(6) Provide information about TB hazards to any contractor who provides temporary or contract employees who will incur occupational exposure (f) Respiratory Protection (f)(1)(i) Provide respirators to employees who: (A) enter isolation rooms or areas (D) repair, replace or maintain air systems or equipment that may reasonably be anticipated to contain aerosolized *M. tuberculosis* (F) work in a residence where an individual with suspected or confirmed infectious TB is known to be present (f)(1)(iii) Provide respirators at no cost and assure that the employee uses the respirator in accordance with this standard (f)(1)(iv) Assure that the employee dons the respirator before entering the work setting and uses it until leaving the work setting All remaining provisions of paragraph (f) are applicable, i.e., (f)(2)—(f)(8) (g) Medical Surveillance All provisions of paragraph (g) are applicable (h) Communication of Hazards and Training (h)(3) Information and Training All elements are applicable (i) Recordkeeping All recordkeeping, except for engineering controls records, is applicable

Chart 4: What Would Be Required for Home Health Care and Home-Based Hospice Care?

In general, most of the provisions of the proposed standard would be applicable for employers providing home health care or home-based hospice care. However, OSHA realizes that home health care providers do not have control over the home environment and therefore, the standard would not require these employers to provide or maintain engineering controls in the homes of their clients. OSHA also realizes that some individuals with infectious TB may be sent home instead of being admitted to the hospital; OSHA would not expect employers to transfer such individuals out of their home. However, individuals with suspected or confirmed infectious TB need to be identified so that home health care providers can take appropriate precautions to protect themselves while in the home.

What Would Be Required for Home Health Care and Home-Based Hospice Care?
(c) Exposure Control (c)(1) Exposure Determination (c)(2)(i) Written Exposure Control Plan including:

What Would Be Required for Home Health Care and Home-Based Hospice Care?
(A) the exposure determination (B) procedures for providing information to occupationally exposed employees about individuals with suspected or confirmed infectious TB or air that may reasonably be anticipated to contain aerosolized *M. tuberculosis* (C) procedures for reporting exposure incidents (c)(2)(v) Employers who provide home health care or home-based hospice care must include procedures for prompt ID of individuals with suspected or confirmed infectious TB, procedures for minimizing exposure to such individuals, a list of high-hazard procedures performed, if any, and procedures for delaying elective high-hazard procedures or surgery until the individual is noninfectious (c)(2)(vii) The exposure control plan must be: (A) accessible (B) reviewed annually and updated whenever necessary (C) available for copying by the Assistant Secretary and Director upon request (d) Work Practices and Engineering Controls (d)(1) Use work practices to eliminate or minimize employee exposure to *M. tuberculosis* (d)(2) Implement the work practices in the Exposure Control Plan (d)(3) Identify individuals with suspected of confirmed infectious TB (d)(6) Provide information about TB hazards to any contractor who provides temporary or contract employees who will incur occupational exposure (f) Respiratory Protection (f)(1)(i) Provide respirators to employees who: (F) work in a residence where an individual with suspected or confirmed infectious TB is known to be present (f)(1)(iii) Provide respirators at no cost and assure that the employee uses the respirator in accordance with this standard (f)(1)(iv) Assure that the employee dons the respirator before entering the work setting and uses it until leaving the work setting All remaining provisions of paragraph (f) are applicable, i.e., (f)(2)–(f)(8) (g) Medical Surveillance All provisions of paragraph (g) are applicable (h) Communication of Hazards and Training (h)(3) Information and Training All elements are applicable except those related to the use of engineering controls (i) Recordkeeping All recordkeeping, except for engineering controls records, is applicable

Chart 5: What Would Be Required for Emergency Medical Services?

Similar to Home Health Care or Home-Based Hospice Care, employers providing emergency medical services do not have control over many of the work settings in which they may provide services. Thus, OSHA would not require these employers to provide or maintain engineering controls. In addition, while these types of employers are likely to be transferring individuals with infectious TB, it is not their responsibility to initiate the transfer of an individual identified as having suspected or confirmed infectious TB to a facility with appropriate isolation capabilities. However, where it is feasible to do so, such individuals need to be identified so that emergency medical service employees can take precautions to protect themselves.

What Would Be Required for Emergency Medical Services?
(c) Exposure Control (c)(1) Exposure Determination (c)(2)(i) Written Exposure Control Plan including: (A) the exposure determination (B) procedures for providing information to occupationally exposed employees about individuals with suspected or confirmed infectious TB or air that may reasonably be anticipated to contain aerosolized *M. tuberculosis* (C) procedures for reporting exposure incidents (c)(2)(iii): (A) Procedures for prompt identification of individuals with suspected or confirmed infectious TB (B)(4) Procedure or policy for using properly-fitted masks on individuals with suspected or confirmed infectious TB (C) A list of high-hazard procedures (c)(2)(vii) The exposure control plan must be: (A) accessible (B) reviewed annually and updated whenever necessary (C) available for copying by the Assistant Secretary and Director upon request (d) Work Practices and Engineering Controls (d)(1) Use work practices to eliminate or minimize employee exposure to *M. tuberculosis* (d)(2) Implement the work practices in the Exposure Control Plan (d)(3) Identify individuals with suspected or confirmed infectious TB (d)(6) Provide information about TB hazards to any contractor who provides temporary or contract employees who will incur occupational exposure (f) Respiratory Protection (f)(1)(i) Provide respirators to employees who: (A) enter an isolation room or area (B) are present during the performance of procedures or services for an individual with suspected or confirmed infectious TB who is not masked (C) transport an individual with suspected or confirmed infectious TB in an enclosed vehicle or who transport an unmasked individual with suspected or confirmed infectious TB within the facility (F) work in a residence where an individual with suspected or confirmed infectious TB is known to be present (f)(1)(iii) Provide respirators at no cost and assure that the employee uses the respirator in accordance with this standard (f)(1)(iv) Assure that the employee dons the respirator before entering the work setting and uses it until leaving the work setting

What Would Be Required for Emergency Medical Services?
All remaining provisions of paragraph (f) are applicable, i.e., (f)(2)–(f)(8) (g) Medical Surveillance All provisions of paragraph (g) are applicable (h) Communication of Hazards and Training (h)(3) Information and Training All elements are applicable except those related to the use of engineering controls (i) Recordkeeping All recordkeeping, except for engineering controls records, is applicable

Chart 6: What Would Be Required for Clinical and Research Laboratories?

Employers in clinical and research laboratories that handle specimens that may contain *M. tuberculosis* or process or maintain the resulting cultures or perform activities that may result in the aerosolization of *M. tuberculosis* must follow most of the provisions of the proposed standard. In addition, a special paragraph has been added to address the unique hazards of the lab environment. Clinical and research labs are not responsible for developing or implementing procedures for the early ID of individuals with suspected or confirmed infectious TB or the transfer of those individuals.

What Would Be Required for Clinical and Research Laboratories?
(c) Exposure Control (c)(1) Exposure Determination (c)(2)(i) Written Exposure Control Plan including: (A) the exposure determination (B) procedures for providing information to occupationally exposed employees about individuals with suspected or confirmed infectious TB or air that may reasonably be anticipated to contain aerosolized *M. tuberculosis* (C) procedures for reporting exposure incidents (c)(2)(iv) Employers who operate a laboratory must include a determination as to whether the facility should operate a laboratory at Biosafety Level 2 or 3 containment and document the need for controlled access, anterooms, sealed windows, directional airflow, measures to prevent the recirculation of lab exhaust air, filtration of exhaust and thimble exhaust connections (c)(2)(vii) The exposure control plan must be: (A) accessible (B) reviewed annually and updated whenever necessary (C) available for copying by the Assistant Secretary and Director upon request (d) Work Practices and Engineering Controls (d)(1) Use work practices and engineering controls to eliminate or minimize employee exposure to *M. tuberculosis* (d)(2) Implement the work practices in the Exposure Control Plan (d)(6) Provide information about TB hazards to any contractor who provides temporary or contract employees who will incur occupational exposure (e) Clinical and Research Laboratories All provisions of paragraph (e) are applicable (f) Respiratory Protection (f)(1)(ii) For research laboratories, provide respirators to employees who are present when aerosols of *M. tuberculosis* cannot be safely contained (f)(1)(iii) Provide respirators at no cost and assure that the employee uses the respirator in accordance with this standard (f)(1)(iv) Assure that the employee dons the respirator before performing the tasks under (f)(1)(ii) and uses it until completing the tasks All remaining provisions of paragraph (f) are applicable, i.e., (f)(2)–(f)(8) (g) Medical Surveillance All provisions of paragraph (g) are applicable (h) Communication of Hazards and Training (h)(1)(i) Labels: (h)(1)(i) Label air systems that may reasonably be anticipated to contain aerosolized *M. tuberculosis* ''Contaminated Air—Respiratory Protection Required'' (h)(1)(ii) Label clinical and research laboratory wastes with the biohazard symbol (h)(2) Signs: (h)(2)(i)(C) Post signs at entrances to clinical and research laboratories where *M. tuberculosis* is present (h)(2)(iv) Include on the sign the biohazard symbol, the name and telephone number of the laboratory director or other designated responsible person, the infectious agent designation *M. tuberculosis,* and special requirements for entering the laboratory (h)(3) Information and Training All elements are applicable (i) Recordkeeping All recordkeeping is applicable

Chart 7: What Would Be Required for Personnel Services?

This category covers employers who provide temporary employees to any of the other employers covered under the scope of the standard (e.g., temporary nurses hired to work at a hospital, temporary lab technicians working in a clinical laboratory). Employees in these situations are covered by the standard in the same manner as other employees who have occupational exposure to tuberculosis. A shared responsibility for worker protection exists between the personnel service employer and the client (or ''host'') employer. These matters may be specified as a matter of contract or employment agreement existing between the personnel service employer and the host employer. In this chart OSHA has assumed that a typical contract or employment agreement exists between the two employers with the personnel provider accepting responsibility for the general requirements and the host employer being responsible for site-specific measures. Therefore, the personnel service provider is shown complying with non-site specific provisions such as exposure determination, medical surveillance, and non-site specific employee training. The host employer would comply with more site-specific

provisions such as procedures for early ID, engineering controls and site-specific employee training. In addition, the chart assumes that the personnel service provider has accepted the responsibility for respiratory protection. OSHA requires that workers in these situations receive full protection under the standard.

What Would Be Required for Personnel Services?
(c) Exposure Control
(c)(1) Exposure Determination
(c)(2)(i) Written Exposure Control Plan including:
(A) the exposure determination
(B) procedures for providing information to occupationally exposed employees about individuals with suspected or confirmed infectious TB or air that may reasonably be anticipated to contain aerosolized *M. tuberculosis*
(C) procedures for reporting exposure incidents
(c)(2)(vii) The exposure control plan must be:
(A) accessible
(B) reviewed annually and updated whenever necessary
(C) available for copying by the Assistant Secretary and Director upon request
(d) Work Practices and Engineering Controls
(d)(1) Use work practices to eliminate or minimize employee exposure to *M. tuberculosis*
(d)(2) Implement the work practices in the Exposure Control Plan
(f) Respiratory Protection
All provisions of paragraph (f) are applicable
(g) Medical Surveillance
All provisions of paragraph (g) are applicable except those related to conducting site-specific follow-up investigations after an exposure incident or skin test conversion
(h) Communication of Hazards and Training
(h)(3) Information and Training
All elements are applicable except those training elements which are site-specific
(i) Recordkeeping
All recordkeeping, except for engineering control records, is applicable

OSHA's preliminary conclusion is that all employees who have occupational exposure to aerosolized *M. tuberculosis*, as a result of performing their duties, are at risk of infection. Under paragraph (a) the Agency has listed those facilities, work settings and services where it believes that significant occupational exposure is most likely to occur. OSHA requests comment and supporting data as to whether there are other work settings or services where significant occupational exposures can be reasonably anticipated.

Paragraph (b) Application

As discussed above, OSHA has preliminarily determined that there are elevated risks of TB infection associated with certain types of work settings and services. However, the Agency realizes that there may be employers covered under the scope of the standard who have work settings in counties where the risk of TB infection is low. Some geographical areas in the U.S. have not reported cases of TB to CDC and facilities in these areas have not encountered any individuals with confirmed infectious TB in their work settings within the recent past.

In consideration of the lessened likelihood of employee exposure in these work settings, OSHA is proposing that some employers be permitted to qualify for a more limited program. Paragraph (b), Application, states that an employer covered under paragraph (a), Scope, other than the operator of a laboratory, may choose to comply only with the provisions of Appendix A if the Exposure Control Plan demonstrates that his or her facility or work setting: (1) does not admit or provide medical services to individuals with suspected or confirmed infectious TB; (2) has not encountered a case of confirmed infectious TB in the past 12 months; and (3) is located in a county that, in the past 2 years, has had no cases of confirmed infectious TB reported in one year and fewer than 6 cases of confirmed infectious TB reported in the other year. Thus, in the past two year period, the number of reported TB cases must be 0 for at least one of the two years. (It may even be zero for both years). In the other year, the number of cases must be no greater than 5. For example, if in the first year of the preceding two-year period the number of reported cases was 0, but in the second year there were 4 reported cases of confirmed infectious TB in the county, an employer would still qualify for the limited program under paragraph (b), provided that none of the cases were encountered in his or her employees' work setting. However, for the employer in this scenario to continue to qualify for the limited program, the number of cases reported in the third year would have to return to zero. Similarly, employers would not qualify for the limited program if the number of cases of confirmed infectious TB reported in the county was greater than zero in both of the preceding two years or if 6 or more cases were reported in one of the preceding two years.

OSHA has taken this approach because the number of TB cases fluctuates widely and different locations and geographical areas may be affected at different times. For example, many counties report no cases in one year or even in two consecutive years, or report a few cases in one year but then have no cases in the following year. From 1992 to 1994 (Ex.7–262), 55.3 percent of the counties in the U.S., representing 12.9 percent of the population, reported no confirmed cases of TB in one year of the preceding two-year period and fewer than 6 cases in the other year. OSHA believes that the approach described above is appropriate given these fluctuations and that it reduces the burden on employers who rarely encounter TB cases by allowing them to qualify for the limited program. OSHA initially considered allowing employers to qualify for the limited program only if there had been no cases of confirmed infectious TB reported in the county in the preceding one-year period. This would have meant that an employer would be required to comply with the full program if even a single case was reported in the county in any year. OSHA requests comment on the approach taken in the proposed rule and the appropriateness of the ''zero-county'' trigger used in the standard.

Although OSHA believes that the risk of incurring TB is substantially reduced in facilities located in counties qualifying for the limited program, the risk of infection continues because all counties have residents who are infected and who may therefore develop active TB and transmit it. In addition, the mobility of the U.S. population means that it is easy to carry the disease from higher risk areas to lower risk areas. Thus, OSHA believes that certain TB exposure control provisions, i.e., those reflected in the limited program required by the standard, need to be in place in all work settings where cases of TB could be encountered.

Under the limited program, employers are responsible for (1) preparing a written exposure control plan with certain minimal elements, (2) providing a baseline skin test and medical history, (3) making medical management and follow-up available after an exposure incident, (4) providing medical removal protection if necessary, (5) providing information and training to employees with potential occupational exposure, and (6) complying with pertinent recordkeeping requirements. The specific paragraphs of the proposed standard that would apply in these situations are outlined in Appendix A.

OSHA believes that these provisions are the minimum requirements necessary for employee protection, even in work settings where no TB has recently been reported in the county and no individuals with confirmed infectious TB have been encountered within the work setting during the past 12 months. OSHA's reasoning is that, although no cases of confirmed infectious TB have been reported for the preceding two years, there is considerable fluctuation among counties from one year to the next, as explained above. In addition, as discussed in the preliminary risk assessment section of the preamble, there is a high prevalence of TB infection nationwide, approximately 6.5 percent. Infections may become active after a latency period of years. Therefore, the absence of a reported active case in the immediate past does not mean that active cases will not be manifested in the current or subsequent years. For these reasons, it is necessary for covered facilities to maintain, at a minimum, a TB program that incorporates the basic TB exposure control provisions that will protect employees from exposures.

A primary element of the limited program is a written exposure control plan. The exposure control plan includes an exposure determination to identify those employees who would incur occupational exposure if an individual with infectious TB were encountered in the work setting. The exposure control plan would also have to contain procedures and policies for the early identification and masking of individuals with suspected or confirmed infectious TB and procedures for transferring those individuals to other facilities. This would assure that if an individual with suspected or confirmed infectious TB were to enter the workplace, he or she would be promptly identified and transferred to a facility with AFB isolation capabilities. In addition, while awaiting transfer, these individuals could be masked to the extent that it is feasible (e.g., in the case of a non-combative individual) in order to prevent transmission. Similarly, the exposure control plan must include procedures for reporting exposure incidents should they occur. Employees need to know what steps to take if an exposure occurs so that appropriate follow-up can be initiated for the medical management of the exposed employee and investigation of the incident.

In order to qualify for the limited program pursuant to paragraph (b), the employer must include in his or her exposure control plan the number of TB cases reported in the county and the number of individuals with confirmed infectious TB who have been encountered within the work setting. An employer is required by the standard to check and document the number of confirmed infectious TB cases in the county once a year. Typically, county health departments collect this information for reporting purposes and report it both on a monthly and an annual basis. Obtaining the annual count from the county health department would meet the requirements of the proposed rule. County case counts must be recorded for the two most recent annual reporting periods, i.e., the two preceding years. This count must be reflected in the employer's Exposure Control Plan, as described below in paragraph (c), Exposure Control Plan, of this Summary and Explanation. The count of cases and the notation in the Plan can be kept in any media, e.g., paper or electronic.

In addition to an abbreviated exposure control plan, the limited program would include some of the basic elements of medical surveillance, i.e., baseline skin tests and medical histories for employees identified under the exposure determination and medical management and follow-up for those employees who have had an exposure incident. Baseline skin tests and histories will help to assure that true conversions are appropriately identified should an exposure incident occur. Medical management and follow-up provisions will assure that exposed employees receive the proper medical evaluation after an exposure incident and that the incident is properly investigated so that it will not occur again. Under this limited program, no periodic medical surveillance would be required.

Where necessary, the employer is also required to provide medical removal and protection (MRP) of benefits for those employees who develop active TB. OSHA anticipates that the need to provide MRP would be a rare event because little active TB has been reported in many of these counties. In addition, if employees are properly trained to identify suspected and confirmed infectious TB and to promptly transfer those individuals, few occupational exposures should occur, thus minimizing the likelihood that employees will become infected. Therefore, training is an important element of the limited program. Training is a key element in assuring that employees know how to identify individuals with suspected or confirmed infectious TB and the necessary steps to take if such an individual is encountered.

Certain minimal records must also be kept by the employer. Medical records for documenting baseline skin tests and any potential medical evaluations made as a result of an exposure incident, as well as records for training and records for OSHA illnesses and injuries, would have to be kept. Keeping records should not be burdensome for the employer since it is likely that only a minimal number of employees would be identified by the exposure determination as having potential occupational exposure (e.g., intake workers in admitting areas or emergency departments); only such employees need medical surveillance or training.

The elements of the limited program outlined under this paragraph closely track the recommendations of the CDC for facilities designated as having ''minimal risk'' under the CDC's TB Guidelines for Health Care Facilities (Ex. 4B). Under these guidelines, CDC considers facilities to have ''minimal risk'' if there is no TB in the community and no TB in the facility. CDC's recommendations for such facilities include a written TB control plan, procedures for early identification and prompt transfer of individuals with suspected or confirmed infectious TB, and employee training. CDC does not specifically recommend baseline skin testing. However, CDC's guidelines do say that baseline testing would be

advisable in these facilities so that, if an unexpected exposure does occur, conversions can be distinguished from positive skin test results caused by previous exposures. CDC also recommends that a risk assessment be conducted by such facilities each year. In the case of a ''minimal risk'' facility, as defined by CDC, this would essentially involve checking on the number of reported cases of TB in the community and within the facility, which is essentially what OSHA requires under the exposure control plan as documentation to qualify for the limited program available under paragraph (b).

Paragraph (c) Exposure Control

Employees incur risk each time they are exposed to aerosolized *M. tuberculosis*. A worker can become infected from a single exposure incident, and thus it is necessary to prevent exposure incidents whenever possible. The goal of this proposed standard is to reduce the significant risk of infection by minimizing or eliminating occupational exposure to aerosolized *M. tuberculosis*.

One purpose of paragraph (c), Exposure Control, is to identify the tasks and procedures where occupational exposure may occur and to identify those employees whose duties include these tasks and procedures. An additional purpose of the paragraph is to develop and document, in an exposure control plan, policies and procedures for eliminating or minimizing occupational exposure, e.g., developing procedures for identifying individuals with suspected or confirmed TB, for appropriately isolating and minimizing employee contact with those individuals, and for reporting exposure incidents.

Paragraph (c)(1) requires each employer who has an employee with occupational exposure to prepare an exposure determination that identifies those employees who have occupational exposure to aerosolized *M. tuberculosis*. As discussed under paragraph (j), Definitions, ''occupational exposure'' means ''reasonably anticipated contact that results from the performance of an employee's duties, with an individual with suspected or confirmed infectious TB or air that may contain aerosolized *M. tuberculosis*.'' Thus, the exposure determination needs to include, in addition to those employees who have direct contact with individuals with suspected or confirmed infectious TB and employees who perform procedures that may aerosolize *M. tuberculosis*, those employees who can reasonably be anticipated as part of their job duties to be exposed to air that may contain aerosolized *M. tuberculosis*.

For example, while an admissions clerk in a homeless shelter will not perform medical procedures on a client with suspected infectious tuberculosis, the clerk may reasonably be anticipated to encounter and share the same airspace with such an individual. Therefore, the admissions clerk would be included in the Exposure Control Plan and would be covered by this standard.

Exposure determination is a key provision of exposure control because the employer must know which tasks or procedures involve occupational exposure in order to determine what measures can be taken to eliminate or minimize exposure incidents. In addition, an exposure determination is necessary in order to ascertain which employees are to be provided with respiratory protection, medical surveillance, and training.

Each employer is required to consider the duties, tasks, and procedures of all employees in each job classification in each work area where occupational exposure occurs when making the exposure determination. OSHA believes that it is appropriate to allow the employer to identify and document job classifications where all or some employees have occupational exposure as a basis for the required exposure determination. By identifying the job classification, each employee included in the description will know that he or she is within the scope of the standard. Listing of every employee's name is not required, however, because that may be burdensome for employers who have many employees with occupational exposure.

The term ''job classification'' is used generically. During the development of the Bloodborne Pathogens standard, commenters used several terms (e.g., ''job category'', ''job responsibility'', ''job title'', ''position description'') to identify and document employees at risk in the exposure determination. OSHA sought to use a term that would encompass all of these terms. Therefore, as in the Bloodborne Pathogens standard, OSHA has chosen to use the term ''job classification'' because it has the broadest application to facilities of all sizes that use formal and less formal designations to classify employees. Thus, the standard would allow employers to use existing job titles, job descriptions, or other designations to identify those job classifications in which occupational exposure occurs. OSHA solicits comment on whether this term needs further defining in this paragraph or in paragraph (j), Definitions.

The standard does not require that every task and procedure that could result in occupational exposure be listed in the exposure control plan, but instead gives the employer a choice in how to document the exposure determination. Paragraph (c)(1)(i) states that the exposure determination shall contain:

> (A) A list of the job classifications in which all employees have occupational exposure; and
>
> (B) A list of the job classifications in which some employees have occupational exposure, and a list of all tasks and procedures (or groups of closely related tasks and procedures) that these employees perform and that involve occupational exposure.

This means that the employer may choose to extend ''blanket'' coverage to those job classifications where essentially all employees have occupational exposure [the paragraph (c)(1)(i)(A) option]. In this case, the employer would not have to list all tasks and procedures for those employees in the exposure control plan, since all of these employees would be covered by the standard. For example, if a hospital determines that all employees within the job classification ''respiratory therapist'' have duties or responsibilities that involve tasks and procedures where occupational exposure occurs, the job classification ''respiratory therapist'' can simply be listed in the exposure determination in accordance with paragraph (c)(1)(i)(A) and no subsequent listing of those tasks and procedures is required. Similarly, the job classification of ''homeless shelter admissions clerk'' in the previous example could be included under the ''blanket'' job classification list in paragraph (c)(1)(i)(A).

On the other hand, the employer may determine that job classifications exist in which only *some* employees have occupational exposure. The employer may determine that it is not necessary to include all employees in such job classifications under the standard since only a portion of them have occupational exposure. In these situations [paragraph (c)(1)(i)(B)], the employer must list the job classification as well as the tasks and procedures or groups of closely related tasks and procedures performed by employees within that job classification that result in occupational exposure. For example, within the job classification ''laboratory technician,'' there may be some employees who experience occupational exposure (e.g., laboratory technicians who perform microbiological procedures on *M. tuberculosis* cultures), while others would not be expected to

have such exposure (e.g., laboratory technicians who work in clinical chemistry). In such a case, the employer may not wish to extend coverage to all employees in the job classification ''laboratory technician''. Consequently, the job classification ''laboratory technician'' would be listed in the exposure determination along with the tasks and procedures in which occupational exposure occurs. This approach would inform employees within the job classification ''laboratory technician'' about those tasks that they perform that involve occupational exposure and that employees performing those tasks and procedures triggers their inclusion in the scope of the standard. However, it would not be necessary for the employer to list each procedure performed by a ''laboratory technician''. For example, performing sputum smears, culturing the bacteria in the sputum, and conducting drug-susceptibility testing on the culture all involve manipulation of specimens that could contain *M. tuberculosis*. Therefore, these tasks could be grouped under the designation ''manipulation of specimens that may contain *M. tuberculosis*.''

Although the standard permits the exposure determination to list job classifications, grouping job classifications according to location would not be sufficient to meet the requirement for identifying job classifications with occupational exposure. For example, identifying job classifications by using the ''Emergency Department'' would not fulfill this requirement because it does not identify the specific employee job classifications that have occupational exposure. An employer who has determined that employees in the ''Emergency Department'' warrant coverage under the standard would have to list the job classifications that involve occupational exposure and identify the tasks and procedures that result in occupational exposure. OSHA believes that merely grouping employees by location, e.g., designating all employees who work in the Emergency Department, may exclude employees who have occupational exposure since such a grouping could overlook employees who may occasionally enter the Emergency Department but are not routinely assigned there. OSHA seeks comment about the protectiveness of permitting exposure determinations to be made by location within a work setting in certain specific instances where the employer believes such a delineation is useful and will not misclassify employees and specifically requests examples of regulatory language that could achieve these objectives.

Paragraph (c)(1)(ii) requires that the exposure determination be made without regard to the use of respiratory protection. It has been OSHA's long-standing position that the determination of occupational exposure be made without regard to the use of personal protective equipment such as respirators. The reason for this is that several conditions must be met for respiratory protection to effectively lessen exposures. First, the employee must be trained to use the equipment properly. Second, respiratory protection must be used each time the task requiring such protection is performed. Third, respiratory protection must fit properly. If even one of these conditions is not fully met, protection cannot be assured. Therefore, all tasks that entail occupational exposure need to be included in the exposure determination, regardless of the use of respiratory protection. This approach is consistent with other OSHA standards (e.g., Bloodborne Pathogens, 29 CFR 1910.1030; Formaldehyde, 29 CFR 1910.1048; Cadmium, 29 CFR 1910.1027) and is essential to designing an appropriate exposure control program. Utilizing this approach assures that workers who perform tasks requiring respiratory protection will receive the training, medical surveillance, and other provisions of this standard that will enhance their safety should respiratory protection fail.

Paragraph (c)(2) requires that each employer covered under the scope of the standard establish a written exposure control plan. The exposure control plan is a key provision of the standard because it requires the employer to identify the employees who receive training, respiratory protection and medical surveillance and to develop a number of policies and procedures that will eliminate or minimize employees' exposure to sources of aerosolized *M. tuberculosis*. However, because not all employers' work settings are the same, not all employers' exposure control plans will need to contain the same elements. The goal of the exposure control plan is to address the type of exposure that occurs in a given work setting, as identified under the exposure determination, and then to develop procedures and policies to minimize or eliminate that exposure. Thus, the size and complexity of the exposure control plan will be relative to the types of exposure encountered in the employer's work setting. For example, social service employees who must provide services to individuals who are in AFB isolation are covered under the scope of the standard. The employer in this case would only have to include certain minimal elements in his or her exposure control plan. This employer would not have to include elements for identifying individuals with suspected or confirmed infectious TB since these individuals will already have been identified by someone else. Similarly, the exposure control plan of such employers would not have to include procedures for isolating or managing the care of individuals with infectious TB. On the other hand, hospitals that admit or provide medical services to individuals with suspected or confirmed infectious TB would be required to have a more extensive exposure control plan since the employer in this case would be responsible for identifying, isolating and possibly performing high-hazard procedures on individuals with suspected or confirmed infectious TB.

Under paragraph (c)(2)(i), the proposed standard requires that the exposure control plan be written. There are several reasons for having the plan in writing. First, because exposure control must be practiced by everyone—employee and employer—it is imperative that an employee be able to find out what provisions are in place in his or her workplace. In addition, the exposure determination gives an employee who may be unfamiliar with the job a ready reference for ascertaining which job classifications, tasks, and procedures entail occupational exposure. Second, the exposure control plan also serves as an on-site adjunct to the overall infection control plan for the work setting and reinforces the employer's training program. Employees will be trained about the various procedures developed by the employer to eliminate and minimize exposure. Having the procedures written and available at the work site will provide a ready reference for employees and will serve as an adjunct to their training. Third, having the plan in writing is also important for enforcement purposes. By reviewing the exposure control plan, an OSHA compliance officer will be able to become familiar with the employer's determination of tasks and procedures with occupational exposure, the job classifications whose duties include those identified tasks, and the policies and procedures the employer uses to minimize occupational exposure along with any revisions to the exposure control plan.

OSHA realizes that many workplaces covered under the scope of the proposed standard may already have comprehensive infection control plans

that may include many of the measures required by the proposed standard. It is not OSHA's intent for employers to duplicate current infection control plans solely for the purpose of complying with the standard. Therefore, the exposure control plan may be comprised of existing documents that are part of a larger infection control plan. However, all elements of the exposure control plan for TB required by the proposed standard must be included. In addition, the plan must be in some manner a cohesive entity by itself or a guidance document must exist that states the overall policy goals and directs the reader to the location of the separate documents that are being used to fulfill the requirements of the standard.

While there will be differences in the elements of employers' exposure control plans, each employer covered under the scope of the standard must have certain minimal elements in his or her plan. Paragraphs (c)(2)(i)(A) through (c)(2)(i)(C) contain the minimal elements that must be included in the exposure control plans of every employer covered under the scope of the standard. Paragraph (c)(2)(i)(A) requires that the exposure control plan must include the exposure determination required under paragraph (c)(1). As discussed above, the exposure determination is necessary to identify those employees who have occupational exposure so that the employer can determine which employees are to be given respiratory protection, medical surveillance and training.

Paragraph (c)(2)(i)(B) requires that the employer develop procedures for informing occupationally exposed employees about suspected or confirmed infectious TB cases and about air that may reasonably be anticipated to contain aerosolized *M. tuberculosis* in order that the employees can take proper precautions against *M. tuberculosis* exposure. Once individuals with suspected or confirmed infectious tuberculosis have been identified, it is necessary to convey this information to employees who may be exposed so that they may take the steps necessary to eliminate or minimize their exposure. When patient confidentiality may be a concern, it is not necessary to use an individual's name to satisfy this provision. For example, lists do not need to be made of all patients in the hospital with active TB. Information may be conveyed to employees by simply labeling the isolation room with the warning sign required under paragraph (h)(2)(iii) while the room is in use for TB isolation. Labeling the room will inform the employees that the individual in the room is in respiratory isolation and the employee must stay out of the room or don the appropriate respiratory protection before entering. Another scenario in which such notification is necessary would be when such an individual must be transported to another facility in an ambulance. In this case, the employees who will be present in the ambulance would have to be notified so that they could utilize proper precautions during the transport.

Paragraph (c)(2)(i)(C) requires that the employer include in the exposure control plan procedures for reporting exposure incidents, including identification of the person to whom the incident is to be reported, and the procedures the employer will use for evaluating the circumstances surrounding exposure incidents as required by paragraph (g)(4)(iv). Under paragraph (j), Definitions, an *exposure incident* * * * is defined as

> * * * an event in which an employee has been exposed to an individual with confirmed infectious TB or to air containing aerosolized *M. tuberculosis* without the benefit of all applicable exposure control measures required by this section.

In the event that unprotected employees are exposed to aerosolized *M. tuberculosis*, it is necessary that this exposure incident be reported to the employer as soon as feasible in order to promptly initiate proper medical management and follow-up of the exposed employee. In addition, quick reporting of exposure incidents permits the employer to investigate the circumstances surrounding such incidents while pertinent conditions remain relatively unchanged and are fresh in the employee's memory.

Procedures need to be in place describing how the exposure incident is to be investigated. Having investigation procedures in place beforehand will help to assure that such investigations are able to be done promptly and in a consistent and thorough manner from case to case. This will assist the employer in complying with the requirement of paragraph (g)(4)(iv) that directs the employer to investigate and document the circumstances surrounding the exposure incident to determine if changes can be instituted that will prevent similar occurrences in the future.

Paragraph (c)(2)(ii) applies to employers who transfer individuals with suspected or confirmed infectious TB to a facility with AFB isolation capabilities. This would apply to employers who operate a facility from which an individual with suspected or confirmed infectious TB is transferred and would not apply to employers whose employees provide certain services such as social welfare services to individuals who have been isolated and in settings where home health care and home hospice care is provided.

The standard does not require any employer to transfer individuals with suspected or confirmed infectious TB. Transfer is an option that employers have that relieves the employer of many provisions of the standard, such as AFB isolation rooms. If an employer chooses to use the transfer option, the employer must include the procedure for implementing the transfer in the exposure control plan.

Paragraph (c)(2)(ii) requires employers who transfer individuals with suspected or confirmed infectious TB to develop exposure control plan procedures that address the following: (1) prompt identification of individuals with suspected or confirmed infectious TB; (2) masking or segregation of individuals with suspected or confirmed infectious TB; and (3) transfer of such individuals to a facility with AFB isolation capabilities.

One of the most important steps in preventing TB transmission is the early detection of individuals who may have infectious TB (Exs. 3–33, 3–34, 3–35, 4B). It is essential that individuals with suspected or confirmed infectious TB be identified as soon as possible so that employees who must have contact with them will be warned early and be able to use appropriate infection control practices to protect themselves from exposure. Obviously, the sooner this is done, the less occupational exposure there will be and the less likely that TB will be transmitted. In addition, early identification of individuals with suspected or confirmed infectious TB will allow for the timely transfer and initiation of effective treatment of those individuals for whom the diagnosis of TB is likely. By promptly administering effective treatment, these individuals can be rendered noninfectious, thus decreasing the time they are infectious and their potential for exposing employees and other people.

OSHA is proposing that employers develop a procedure for the prompt identification of individuals with suspected or confirmed infectious TB as part of the exposure control plan. In order to assure prompt identification, it is necessary for the employer to have procedures in place regarding how this identification will be made. CDC has recommended that identification procedures be based on the prevalence and characteristics of TB in the population served by the specific facility (Ex. 4B). For example,

individuals who come from communities with a high prevalence of TB and exhibit certain signs of TB may be more highly suspected as having infectious TB than individuals from communities with a low prevalence of TB. OSHA, therefore, expects that the procedures may be different depending upon the local conditions.

The procedure needs to contain the following:

Methodology—The employer must describe how he or she will make the determination that an individual should be considered as having suspected or confirmed infectious TB. There are several ways of doing this. The employer can use information provided by a physician or other health care provider in advance of an individual's admission to the employer's facility that the individual has been diagnosed with suspected or confirmed infectious TB. If this is not available the employer must determine whether an individual should be considered as having suspected infectious TB. OSHA defines suspected infectious TB as:

> * * * a potential disease state in which an individual is known, or with reasonable diligence should be known, by the employer to have one or more of the following conditions, unless the individual's condition has been medically determined to result from a cause other than TB: (1) to be infected with *M. Tuberculosis* and to have the signs or symptoms of TB; (2) to have a positive acid-fast bacilli (AFB) smear; or (3) to have a persistent cough lasting 3 or more weeks and two or more symptoms of TB, e.g., bloody sputum, night sweats, anorexia, weight loss and fever. An individual with suspected infectious TB has neither confirmed infectious TB nor has he or she been medically determined to be noninfectious.

Although the definition specifies the criteria the employer must incorporate in his or her plan, the employer will still need to exercise judgment in determining whether an individual meets one or more prongs of the definition. Of course, an employer, such as one who operates a facility in an area of particularly high TB prevalence, is free to use more stringent (i.e., additional) criteria for considering an individual to have suspected infectious TB in his or her particular work setting.

In situations where a medical diagnosis is not available either before or at the time of admission, an employer must collect the information he or she needs to make the determination. This can be accomplished in two ways. The employer can have an employee administer a medical history questionnaire to individuals seeking services from the facility. Another way to obtain information to make this determination is by having an employee observe the individual to ascertain his or her health status, looking for the signs, and asking about the symptoms included in OSHA's definition that may indicate infectious TB. Many employers will use both questionnaires and observation. The employee collecting the information will have to be trained on how to conduct the investigation effectively and with respect for the privacy of the individual.

Responsibilities—The employer must designate responsibilities for determining whether an individual should be considered as having suspected or confirmed infectious TB. However, all employees need to be given clear instructions regarding their roles in the prompt identification of suspected or confirmed infectious TB cases. For example, the health care workers who are the first points of contact in ambulatory care settings and emergency rooms in hospitals could be involved with the initial screening of patients. They may be given several questions to ask a patient, which would be used as information to begin the determination. The next actions would depend upon the responses, and the authority of the health care workers. Some employees, for example, would only report answers to questions or their observation of signs of infectious TB in the client population to someone more knowledgeable. Other employees would be making determinations. The hospital would probably have a different procedure that would be used before or at admission to the hospital for scheduled services. The same hospital might have still another procedure designating responsibility to other employees for identifying patients who develop TB while in the hospital. The Exposure Control Plan must designate those employees who make the determination as to whether an individual has suspected or confirmed infectious TB. An employer should consider such designation(s) carefully because, regardless of who determines that an individual has suspected infectious TB, it is the employer who is responsible for ensuring that the employee knows and uses the proper criteria.

The identification procedures will likely vary among establishments, depending upon the type of work done in the facility. For example, facilities that provide long-term care for the elderly will likely have a different procedure from hospitals that have an open admissions policy. OSHA also expects that the methods different employers use may vary depending on whether the employer is in an area of high or low TB prevalence. This approach is consistent with CDC recommendations.

Promptness—Prompt identification of an individual with suspected or confirmed infectious TB is important because it allows isolation before the disease is spread through the facility. CDC recommends that procedures be in place for prompt identification. However, OSHA expects that the determination will be made as soon as reasonably practical since an employer cannot always make such a determination immediately. For many situations, such as those occurring in a hospice, the employer will have information regarding an individual's health status prior to admitting the individual to the facility. The employer can use this information to determine whether the individual should be considered as having suspected or confirmed infectious TB. In a long-term health care facility, the employer needs to be continually aware of each resident's health status because it can change rapidly. Information regarding the signs or symptoms suspected infectious TB needs to be reported and processed as soon as possible.

Effectiveness—OSHA believes that an effective procedure, when implemented, will identify individuals as having suspected or confirmed infectious TB. OSHA believes that many employers affected by this proposed standard currently use effective procedures and find them to be practical. However, OSHA also recognizes that it will not be possible to ensure that the identification procedure will promptly detect all individuals with infectious TB each time. In homeless shelters, for example, the clients may withhold information requested in a questionnaire because they believe that such information may persuade the shelter to refuse to admit them. Therefore, homeless shelters may have to place greater reliance on observation of the residents for the cluster of signs and symptoms associated with infectious TB. Although this standard would require that homeless shelter workers and others be trained to look for signs in individuals, it is unlikely that all cases will be identified. However, if the employer finds that individuals with suspected and confirmed infectious TB are not being identified, the employer must investigate in order to determine what procedures need to be modified. During an inspection, an OSHA compliance officer will review the adequacy of the procedures, and although a citation would not be issued solely on the basis of failure to identify an individual with suspected infectious TB because no identification system is fool-proof,

failure to identify a number of individuals with undetected suspected or confirmed infectious TB would be good evidence that the procedures or their implementation need to be investigated and improved and could result in a citation.

The employer must also include in the exposure control plan procedures for transferring individuals with suspected or confirmed infectious TB to facilities with AFB isolation capabilities. The procedures must address how those transfers are to take place in order that the transfers may be conducted promptly and with minimal exposure to employees. Specifically, they will include where the cases are to be transferred, how the transfer will occur, and what precautions employees are to take while individuals with suspected or confirmed TB are awaiting transfer.

As the note to paragraph (c)(2)(ii) states, an employer's duties regarding transfer of an individual with suspected or confirmed infectious TB will vary with the type of facility the employer operates and the work performed by his or her employees. For example, the transfer responsibilities of hospitals, long-term care for the elderly, correctional facilities, and hospices may include contacting the receiving facility, providing transport, and taking other steps to ensure the individual can get to the receiving facility. These types of facilities often exercise custodial care over such individuals and, hence, have more responsibility for assuring completion of the transfer. Conversely, the responsibilities a homeless shelter or a facility that offers drug treatment for drug abuse, but that does not have custody over individuals, may only include providing information about the receiving facility, contacting the facility, and providing directions to the facility. An employer who provides home health care or home-based hospice care has no obligation to transfer an individual from his or her home to a receiving facility. Transferring an individual with suspected or confirmed infectious TB protects employees within the facility by making sure the source of occupational exposure is removed and, of course, benefits the individual in that he or she receives help in locating and getting to a receiving facility with the capability for appropriately managing their care.

Paragraph (c)(2)(iii) outlines the additional elements required of employers who have work settings where individuals with suspected or confirmed infectious TB are admitted or provided with medical services. Paragraph (c)(2)(iii)(A) requires that their exposure control plans include procedures for the prompt identification of individuals with suspected or confirmed infectious TB. As discussed above, the early identification of individuals with infectious TB will help to assure that employees who must have contact with those individuals will be warned early and be able to use appropriate infection control practices to protect themselves from exposure. In addition, for employers who have facilities where individuals with suspected or confirmed infectious TB are admitted and provided medical services, prompt identification is essential so that isolation precautions and effective treatment can be initiated as soon as possible, thereby reducing exposure to employees and other people.

Paragraph (c)(2)(iii)(B) requires that the employer develop procedures for isolating and managing the care of individuals with suspected or confirmed infectious TB. Having isolation procedures in place will help to assure that employees are aware of the steps to take in the event that individuals with suspected or confirmed infectious TB are identified. If employees know the proper procedures to follow, they will be better equipped to initiate isolation promptly, thereby reducing the likelihood that individuals with infectious TB will infect others. This provision is in accordance with the most recent CDC guidelines, which also recommend the procedures include:

(1) The indications for isolation, (2) who is authorized to initiate and discontinue isolation, (3) isolation practices, (4) monitoring of isolation, (5) management of patients who will not comply with isolation practices, and (6) criteria for discontinuing isolation. (Ex. 4B)

While OSHA allows the employer to determine what criteria should be included in the procedures to isolate, the Agency believes that it is prudent for the employer also to consider the elements listed in the CDC guidelines.

Paragraph (c)(2)(iii)(B) also requires that the employer develop policies and procedures for managing the care of individuals with suspected or confirmed infectious TB once they have been placed in isolation. The exposure control plan must include procedures and polices addressing: (1) Minimization of the time an individual with suspected or confirmed infectious TB remains outside of an AFB isolation room or area, (2) minimization of employee exposure in AFB isolation rooms or areas, (3) delay of elective transport or relocation of individuals with infectious TB within the facility and, to the extent feasible, performance of services or procedures for such individuals in an AFB isolation room or area, (4) masking of individuals with infectious TB or use of portable containment engineering controls during transport outside of AFB isolation rooms and return of the individual to an AFB isolation room or area as soon as is practical after completion of the service or procedure, and (5) delay of elective high-hazard procedures and elective surgery until an individual with suspected or confirmed infectious TB is determined to be noninfectious.

It is important to minimize, to the extent feasible, exposure of employees to aerosolized *M. tuberculosis* even while maintaining a high quality of health care and other required services. Developing policies and procedures addressing the items listed above will help to assure that this overall goal is met. For example, there may be times when an individual with suspected or confirmed infectious TB must leave the isolation room or area (e.g., when certain equipment necessary for providing care to the patient cannot be brought into the room). On these occasions having policies in place that minimize the time those individuals must be outside the isolation room or area will help to reduce the likelihood that droplet nuclei are spread. For example, if a particular procedure must be performed outside of the isolation room, time could be minimized by taking the individual directly to the procedure area, performing the procedure upon arrival, and returning the individual to isolation immediately after completion of the procedure. In addition, if a procedure is to be performed outside of the isolation room, a time could be chosen when the procedure area is not being used by others.

The exposure control plan must also contain procedures for minimizing employee exposure in AFB isolation rooms or areas. For example, policies addressing minimizing both the number of employees and time that such employees spend in isolation rooms can reduce exposure. This can be accomplished in a variety of ways. For example, in order to minimize the number of employees entering an isolation room, certain tasks or procedures that might normally be done by several different employees could be done by one person. A nurse coming into the room to administer daily TB treatment could also bring in the patient's breakfast at the same time rather than have a hospital dietician deliver the meal. In addition, the

employer must address minimization of time that employees spend in an isolation room or area. For example, rather than conducting an entire discharge planning interview with an individual in person, the employee may be able to collect and convey a large part of the information over the phone with the individual. Personal contact could be limited to just the time needed to obtain items requiring direct interaction, such as the individual's signature.

Policies are to be included that address the masking of individuals with infectious TB during transport outside of AFB isolation rooms or areas. Masking of individuals may be accomplished, for example, through the use of surgical masks or valveless respirators. A barrier such as a surgical mask, when placed over the mouth of an individual who is coughing, will reduce the formation of droplet nuclei because the mask will collect and contain the droplets as they are discharged before they have time to evaporate and form droplet nuclei. A respirator that does not have an exhalation valve can also be used to capture droplets being discharged. An exhalation valve would permit droplets to pass through and discharge into the air, where they could evaporate and form droplet nuclei. However, while surgical masks prevent the formation of droplet nuclei, they do not prevent exposure to droplet nuclei. As the document ''Biosafety Precautions for Airborne Pathogens'' states:

> There is no reciprocity between the means of prevention of the actual formation of droplet nuclei (coughing into a tissue) and the means of prevention of exposure (barriers to breathing in the droplet nuclei). Once a droplet nucleus has been allowed to form, its small size can penetrate the fiber of a tissue or a surgical mask. Thus these products do not represent adequate physical barriers to the aerosol transmission of droplet nuclei. The appropriate barrier is a well fitted respirator that does not allow leakage of air around the edges and blocks passage of microorganisms in the filter media (fibers or pores) through which air is inspired. Although a simple surgical mask applied to a tuberculosis patient who must be transported outside the isolation room will prevent the dispersal of organisms as droplet nuclei, such a mask does not provide adequate protection to the individual who must breathe air containing droplet nuclei. (Ex. 7–134)

Since masking of an individual with suspected or confirmed infectious TB will reduce the number of droplet nuclei expelled into the air, the employer is required to develop policies addressing the masking of such individuals during transport outside of an AFB isolation room.

It is not OSHA's intent to dictate patient management practices, nor will it be the Compliance Officer's responsibility to determine the correctness of certain patient management policies. However, the Agency believes that the employer must consider the above situations and develop policies that address them, keeping in mind the goal of minimizing employee exposure. This provision is in accordance with CDC recommendations (Ex. 4B).

The exposure control plan must also contain policies for the delay of elective transport or relocation within the facility of individuals with suspected or confirmed infectious TB outside of an AFB isolation room or area. For example, delaying the transfer of an inmate with suspected or confirmed infectious TB from one prison to another, where possible, until the inmate has been determined to be noninfectious, will reduce not only the number of employees exposed, but will also minimize the exposure of other inmates, thereby decreasing the risk of transmission of disease.

Similarly, the exposure control plan is to include policies for the delay of elective high-hazard procedures until an individual with suspected or confirmed infectious TB has been determined to be noninfectious. Elective high-hazard procedures (e.g., pulmonary function testing) or elective surgery (e.g., noncritical dental procedures) might be easily delayed, without compromising care, until an individual with infectious TB has been determined to be noninfectious.

Paragraph (c)(2)(iii)(C) requires the employer to list all high-hazard procedures performed in the workplace. As discussed in paragraph (j), Definitions, high-hazard procedures are defined as ''* * * those procedures performed on an individual with suspected or confirmed infectious tuberculosis in which the potential for being exposed to *M. tuberculosis* is increased due to the reasonably anticipated generation of aerosolized *M. tuberculosis* * * *'' Under paragraph (d)(4) of Work Practice and Engineering Controls, the proposed standard requires that all employers assure that high-hazard procedures are conducted in an AFB isolation room or area. Thus, listing the high-hazard procedures will serve to identify those procedures that require special ventilation considerations (e.g., maintaining negative pressure and properly exhausting contaminated air). This will assist employees in determining which procedures must be performed using such engineering controls and, consequently, will help minimize employee exposure.

For employers who have work settings where TB cases are isolated, paragraph (c)(2)(iii)(D) requires the employer to develop a schedule for the inspection, maintenance, and performance monitoring of engineering controls. Engineering controls required by the proposed standard play an essential role in reducing employee exposures to *M. tuberculosis.* Thus, it is necessary that these controls be appropriately maintained, inspected and monitored in order to assure that they are functioning properly. Since engineering controls are mechanical systems, they are prone to occasional lapses in performance caused by occurrences such as clogged filters, slipping or broken drive belts, burned-out motors, obstructed ducts, and so forth. Since these situations cannot be predicted, it is necessary to regularly inspect engineering controls for proper functioning. Hence, a schedule must be developed for such activities. In addition, employees who are responsible for the maintenance will have a record that they can check to see when certain engineering controls need to be inspected, maintained or monitored. In general, OSHA has left the time frame for these activities up to the employer, except as required under paragraphs (d)(5)(ii) and (d)(5)(iii), since the employer is familiar with the characteristics of the workplace that could affect the performance of these controls (e.g., dusty conditions, high heat and humidity, seasonal variations).

For facilities with clinical or research laboratories, Paragraph (c)(2)(iv) requires that the exposure control plan contain a determination from the director of the laboratory as to whether the laboratory facility should operate at Biosafety Level 2 or 3 containment according to CDC/NIH recommendations. Under paragraph (e), Clinical and Research Laboratories, the proposed standard requires a number of provisions to eliminate or minimize exposure in clinical and research laboratory settings. These provisions are based on CDC/NIH recommendations (Ex. 7–72) for laboratory procedures performed under Biosafety Levels 2 and 3 for an infectious agent such as *M. tuberculosis*. However, as noted in the CDC/NIH recommendations, the selection of a biosafety level depends on a number of factors and it may be necessary to adapt the biosafety level based upon such factors. For example, the CDC/NIH recommendations state that:

Occasions will arise when the laboratory director should select a biosafety level higher than that recommended. For example, a higher biosafety level may be indicated by the unique nature of the proposed activity (e.g., the need for special containment for experimentally generated aerosols for inhalation studies) or by the proximity of the laboratory to areas of special concern (e.g., a diagnostic laboratory located near patient care areas). Similarly, a recommended biosafety level may be adapted to compensate for the absence of certain recommended safeguards. For example, in those situations where Biosafety Level 3 is recommended, acceptable safety may be achieved for routine or repetitive operations (e.g., diagnostic procedures involving the propagation of an agent for identification, typing and susceptibility testing) in laboratories where facilities satisfy Biosafety Level 2 recommendations, provided the recommended Standard Biological Practices, Special Practices, and Safety Equipment for Biosafety Level 3 are rigorously followed. (Ex. 7–72, pg. 70)

OSHA agrees that it is appropriate that such decisions be made by the laboratory director and would allow such adaptations to the CDC/NIH recommendations. However, regardless of adaptations, OSHA requires the laboratory director to determine and document the need for controlled access, anterooms, sealed windows, directional airflow, preventing recirculation of laboratory exhaust air, filtration of exhaust air before discharge outside, and thimble exhaust connections for biological safety cabinets. These determinations, along with any adaptations to the CDC/NIH biosafety level, must be made a part of the exposure control plan. The documentation will provide information to the laboratory employees of adaptations to and changes in recommended biosafety levels.

For employers who provide home health care or home-based hospice care, paragraph (c)(2)(v) specifies the elements that are to be included in the exposure control plan. In home health care and home-based hospice care situations, individuals are in their private homes receiving health care and other services and thus the employer has limited control over the work site in which he or she provides those services. In addition, employers providing such home-based care will not be transferring individuals identified as having suspected or confirmed infectious TB from their homes to facilities with isolation capabilities, nor will the employer be initiating isolation precautions in the home. In recognition of the uniqueness of home-based work settings, OSHA has limited the elements of the exposure control plan for an employer who provides home health care and home-based hospice care. The elements included under this paragraph are intended to address the type of activities that are likely to occur in the home health care work setting. Under this paragraph the employer must include procedures for prompt identification of individuals with suspected or confirmed infectious TB and for minimizing employee exposure to such individuals. As discussed above, in order for employees to take proper precautions in protecting themselves from exposure to TB, it is essential that there be procedures to identity potentially infectious individuals. In many cases the home health care employer may already know that the individual has been identified as having suspected or confirmed infectious TB and has been confined to their home. However, in other cases, an individual may be suffering from other immunocompromised conditions and may develop active TB. Because employees in home health care and home-based hospice care may be providing services to individuals at risk of developing active TB, it is necessary that there be procedures in place for identifying those individuals. In addition, the exposure control plan must include procedures for minimizing employee exposure. Such procedures might include minimizing the time spent in the home by combining tasks to limit the number of entries or by minimizing the number of employees who must enter the home along with the time they spend there. Paragraph (c)(2)(v) also requires that the exposure control plan include a list of high-hazard procedures, if any, performed in the workplace and procedures for delaying elective high-hazard procedures until the individual is noninfectious. Listing the high-hazard procedures will serve to identify those procedures that may require special considerations. In the home setting, this would not include the use of AFB isolation precautions. To the extent possible the employer should also include procedures for when these types of procedures can be delayed. This will decrease the exposure of employees to aerosolized *M. tuberculosis* that might be generated performing these procedures.

Paragraph (c)(2)(vi) stipulates that the employer must document the number of confirmed infectious tuberculosis cases encountered in the work setting in the past 12 months in the Exposure Control Plan whenever the employer is using this information to claim reduced responsibilities related to paragraph (b), Application, and paragraph (g)(3)(iii)(D), Medical Surveillance, of the standard. Under paragraph (b), employers are relieved from implementing certain provisions of the standard if they do not admit or provide medical services to individuals with suspected or confirmed infectious TB and they can demonstrate that, in the past 2 years, there have been no cases of confirmed infectious TB reported in the local county in one or both years and, if any cases have occurred in one of the past 2 years, fewer than 6 confirmed infectious cases were reported in that year. Furthermore, employers desiring to follow the limited program must demonstrate that no such cases have been encountered in his or her employees' work setting in the past 12 months. Under paragraph (g)(3)(iii)(D) of Medical Surveillance, employees with negative TB skin tests are to be provided with a TB skin test every 6 months if the employee works in an intake area where early identification procedures are performed in facilities where six or more individuals with confirmed infectious TB have been encountered in the past 12 months. However, if the employer can document that fewer than 6 individuals with confirmed infectious TB have been encountered in the facility, the employee in the intake area would only have to be provided with a TB skin test annually. The count of the number of confirmed infectious TB cases in the exposure control plan would serve to document that fewer than 6 individuals with confirmed infectious TB had been encountered in the past 12 months, thus relieving the employer of the burden of providing skin tests every 6 months for those affected employees.

Paragraph (c)(2)(vii)(A) requires that a copy of the exposure control plan be accessible to employees. The reason for this is to assure that an employee can get and consult the exposure control plan within a reasonable time, place and manner. Having access to the plan encourages employees to develop a complete understanding of the plan and its application, so that the program can be carried out by both employer and employees. Having the plan available also serves as an on-site adjunct to the overall infection control program and may reinforce the training programs.

For fixed work sites and primary workplace facilities, the plan must be maintained on-site at all times. For those situations where an employee(s) travels between work sites or where the employee's work is carried out at more than one geographical location, the plan may be maintained at the primary workplace facility. To ensure access, the plan should be in a central location

where an employee may see it whenever he or she wishes. However, in order to allow flexibility, OSHA is not specifying where the plan must be kept. The employer is permitted to determine where the plan is kept provided that the employee can access a copy of the plan at the workplace, within the workshift. For example, if the plan is maintained on a computer, access to the computer or hard copy must be available to the employee. Likewise, if the plan is comprised of several separate policy documents, copies of all documents must be accessible in addition to any general policy statement or guiding document that may exist.

Paragraph (c)(2)(vii)(B) requires that the exposure control plan be reviewed at least annually and updated whenever necessary to reflect new or modified tasks, procedures, or engineering controls that affect occupational exposure and to include new or revised employee positions with occupational exposure. An example of such a situation would be when an employer in a facility that had previously transferred individuals with suspected or confirmed infectious TB decided that such individuals would be admitted and provided medical services. The purpose of this requirement is to assure that all new tasks and procedures are evaluated in order to determine whether they could result in occupational exposure. New and revised job classifications must be added to the lists of job classifications and tasks and procedures identified in (c)(1)(i) of this section in order to assure full coverage of occupationally exposed employees. The updating must occur as soon as feasible and may not be postponed until the annual review.

Paragraph (c)(2)(vii)(C) requires that the exposure control plan be made available to the Assistant Secretary and the Director upon request for examination and copying. The purpose of this requirement is to allow the OSHA representative to review an employer's plan, including the exposure determination of employees at risk for occupational exposure. Although the Assistant Secretary or the Director could request the plan at any time, it will usually be requested by an OSHA compliance safety and health officer (CSHO) during the course of a workplace inspection. The CSHO needs to examine the plan in order to see what procedures and program planning for the control of occupational exposures have been instituted and whether they meet the requirements of the standard.

Paragraph (d) Work Practices and Engineering Controls

It is generally acknowledged that protection of the employee is most effectively attained by elimination or minimization of the hazard at its source, which engineering controls and work practices are both designed to do. Industrial hygiene principles also teach that control methods that depend upon the vagaries of human behavior are inherently less reliable than well-maintained mechanical methods. For these reasons, OSHA has preferred engineering and work practice controls and has required, under paragraph (d)(1), that they be used to eliminate or minimize employee exposure to *M. tuberculosis.* Nevertheless, OSHA recognizes that situations may exist in which neither of these control methods is feasible and that, in these circumstances, employee protection must be achieved through the use of personal protective equipment, primarily respirators. In other situations, personal protective equipment may have to be utilized in conjunction with engineering controls and/or work practices to obtain a further reduction in employee exposure.

Engineering controls serve to reduce employee exposure in the workplace by either removing the hazard or isolating the worker from exposure. These controls include process or equipment redesign, process or equipment enclosure (e.g., biosafety cabinets), and employee isolation. In general, engineering controls act on the source of the hazard and eliminate or reduce employee exposure without reliance on the employee to take self-protective action.

In comparison, work practice controls reduce the likelihood of exposure through alteration of the manner in which a task is performed (e.g., closing the door of an AFB isolation room immediately upon entering or exiting). Although work practice controls also act on the source of the hazard, the protection they provide is based upon employer and employee behavior rather than installation of a physical device. In many instances these two control methodologies work in tandem, because it is often necessary to employ work practice controls to assure effective operation of engineering controls. Under the provisions of the preceding paragraph, Exposure Control Plan, the employer is required to develop a number of work practices relative to controlling occupational exposure to TB. In paragraph (d)(2), these work practices are required to be implemented in the work setting.

In developing the methods of compliance section for this proposal, OSHA carefully considered the work environments that have the potential for producing occupational exposures. Since the source of the hazard is frequently a living person, typical methods of reducing or eliminating the hazard at the source may not always be feasible. For example, in an industrial operation a process may be entirely enclosed and operated or monitored by an employee at a remote location, a situation that would rarely, if ever, occur in the work settings covered by this standard. The Agency believes, therefore, that prevention of exposures to *M. tuberculosis* will often require use of a combination of control methods to achieve adequate protection of employees. Paragraph (d)(1) requires work practices and engineering controls to be used to eliminate or minimize employee exposures.

Not all facilities will have the capabilities to admit or provide medical services to individuals with suspected or confirmed infectious tuberculosis. Consequently, these facilities will have to transfer such individuals to another facility where isolation rooms or areas are available. Paragraph (d)(3) requires that individuals with suspected or confirmed infectious TB must be identified and, except in settings where home health care or home-based hospice care is provided, shall be: (i) masked or segregated in such a manner that contact with employees who are not wearing respiratory protection is eliminated or minimized until transfer or placement in an AFB isolation room or area can be accomplished; and (ii) placed in an AFB isolation room or area or transferred to a facility with AFB isolation rooms or areas within 5 hours from the time of identification, or temporarily placed in AFB isolation within 5 hours until placement or transfer can be accomplished.

Masking or segregation of individuals with suspected or confirmed infectious TB while those individuals are awaiting placement in isolation or transfer to another facility is done to assure that employee exposure is minimized to the extent feasible. This provision, drawn from CDC recommendations (Ex. 4B), is aimed at minimizing the exposure of employees in areas where individuals are first identified as having suspected or confirmed infectious TB. Although CDC recommends masking such individuals, OSHA presents a choice of masking or segregation because the Agency believes that this practice is directly involved with the medical management of such individuals. It is OSHA's mission to protect employees

from occupational exposure to tuberculosis and it is not the Agency's intent to dictate medical practice relative to individuals with suspected or confirmed infectious TB. Therefore, where the employer has chosen not to mask individuals with suspected or confirmed infectious TB when they are not in isolation rooms or areas or when such individuals cannot be masked (e.g., because they are combative), the employer must segregate these individuals in a manner such that contact with employees who are not wearing respiratory protection is eliminated or minimized. Segregation could be accomplished, for example, by having the individual wait in an area out of the main traffic of a waiting room or intake area or in a vacant examination room that is not needed for patient/client consultations. The time that a facility can permit an individual to await placement or transfer is limited to 5 hours. After that the individual must be placed in isolation.

The primary purposes of AFB isolation rooms or areas are to (1) isolate patients who are likely to have infectious TB from unprotected employees, (2) prevent escape of droplet nuclei from the room, thus preventing entry of *M. tuberculosis* into the corridor and other areas of the facility where unprotected employees may be exposed, and (3) provide an environment that will promote reduction of the concentration of droplet nuclei through various engineering controls (Ex. 4B). All of these will reduce employee exposure. Indeed, placement of individuals with suspected or confirmed infectious TB in an AFB isolation room is the most effective way to prevent or lessen transmission.

OSHA has proposed that individuals with suspected or confirmed infectious TB be isolated or transferred within 5 hours from the time of being identified as a suspected or confirmed case. The Agency realizes that the time it will take to isolate or transfer an individual once he or she is identified as having suspected or confirmed infectious TB may vary and that circumstances may arise that cause delays in initiating isolation (e.g., all isolation rooms may be occupied by other patients). However, OSHA is also concerned about the amount of time an individual, who has been identified as having suspected or confirmed infectious TB, should be permitted to stay in non-isolation areas. Individuals who must wait for extended periods of time before placement in AFB isolation or transfer may present a risk of exposure to employees working in these areas even though these individuals may be masked. A study by Moran et. al. shows that emergency departments that made a presumptive diagnosis of TB were able to initiate isolation in an average of 5 hours from the time of patient registration (Ex. 7–251). Patient registration usually precedes identification. The standard requires that procedures be in place for prompt identification of individuals with suspected or confirmed infectious TB. In view of this requirement and the fact that the study was based on time elapsed from patient registration to isolation, which included the time the patient waited to be medically observed, the Agency has preliminarily concluded that five hours from the time of being identified is a reasonable cutoff point for transfer or placement in isolation.

The Agency's concern regarding permitting identified individuals to wait for extended periods, even though they are masked, before they are transferred or isolated is not unfounded. The American Thoracic Society, in its document Control Of Tuberculosis In The United States, states:

> * * *Patients unable to cooperate in covering coughs and sneezes can wear ordinary surgical masks for *short periods,* for example, while being transported within institutions. For *longer periods,* masks on patients are stigmatizing, uncomfortable, and probably ineffective. (Ex. 5–80) (emphasis added)

Consequently, a cutoff point of 5 hours has been proposed as the maximum amount of time individuals who have been identified with suspected or confirmed infectious TB may await transfer or placement into AFB isolation. As discussed under the Exposure Control Plan, paragraph (c), employers are required to have procedures in place for isolating or transferring individuals identified with suspected or confirmed infectious TB so that AFB isolation can be executed expeditiously. Five hours would appear to be a reasonable amount of time to carry out these procedures. OSHA believes that longer periods of time are likely to pose too great a risk of exposure to employees in the vicinity. The longer an individual with suspected or confirmed infectious TB remains outside of AFB isolation, the greater the risk of transmission.

It should be noted that the 5-hour cutoff is the amount of time allotted *per facility* to accomplish AFB isolation or transfer of these individuals. More specifically, if an individual spent 4 hours awaiting transfer at an identifying facility, the receiving facility would still be allowed 5 hours to accomplish isolation, not just the one hour remaining since initial identification of the individual. The intent of the proposed facility-based 5-hour period is to allow the receiving facility adequate time to accomplish isolation and to recognize that the receiving facility should not be held responsible for circumstances beyond the facility's control (e.g., the time the individual waited before arrival at the receiving facility).

If placement or transfer cannot be completed within five hours, it must be done as soon as possible thereafter. In addition, the employer must assure in such a case that his or her facility has AFB isolation rooms or areas for the isolation of the individual until placement or transfer can be accomplished. More specifically, it is not necessary to construct a dedicated AFB isolation room or area to isolate such individuals while awaiting transfer or placement within the facility. The definition of ''AFB isolation room or area'' states that this may be a room, area, booth, tent, or other enclosure that is maintained at negative pressure to adjacent areas in order to control the spread of aerosolized *M. tuberculosis.* For example, such isolation might be achieved by placing a portable stand-alone HEPA filtration unit (vented to the outside) in an unused examination room. Another method is the use of a rigid enclosure on casters with a ventilation unit to achieve negative pressure, a window kit to safely exhaust the enclosure's air to the outside, and a digital pressure monitor to assure maintenance of negative pressure within the enclosure. As is the case with any AFB isolation room or area, the means used to isolate an individual awaiting placement or transfer must achieve negative pressure and have its air safely discharged to the outside. OSHA seeks comment regarding the 5-hour limit on placement or transfer and measures that can be used for AFB isolation in those situations when transfer or placement cannot be accomplished within that time.

Paragraph (d)(4) stipulates that high-hazard procedures must be conducted in AFB isolation rooms or areas. High-hazard procedures as defined in paragraph (b), Definitions, are procedures performed on an individual with suspected or confirmed infectious TB in which the probability of *M. tuberculosis* being expelled into the air is increased. These procedures include, but are not limited to, endotracheal intubation and suctioning, diagnostic sputum induction, aerosol treatments (including pentamidine therapy), pulmonary function testing, and bronchoscopy. These procedures also include autopsy, clinical, surgical, and laboratory procedures that may

aerosolize *M. tuberculosis.* In view of the increased probability of droplet nuclei generation associated with these procedures, all high-hazard procedures are required to be performed in rooms, areas, or booths that meet AFB isolation criteria (e.g., negative pressure) in order to contain the droplet nuclei and eliminate or minimize employee exposure. Other procedures that may generate aerosols (e.g., irrigation of tuberculous abscesses, homogenizing or lyophilizing infectious tissue), are also covered by this provision. (See paragraph (e) of this proposal for requirements for microbiological practices and containment equipment in laboratories.)

Paragraph (d)(5) requires that engineering controls be used in facilities that admit or provide medical services or AFB isolation to individuals with suspected or confirmed infectious TB except in settings where home health care or home-based hospice care is being provided. For example, engineering controls must be used in isolation rooms or areas, areas where high hazard procedures are performed, and autopsy rooms where *M. tuberculosis* may be aerosolized. This provision specifically excepts settings where home health care or home-based hospice care is being provided. In such situations, the employer is not in control of the employee's work setting because the setting is the private home of the individual being provided with care. In view of this, an employer providing home health care or home-based hospice care would not be required to implement engineering controls in the individual's home.

In conjunction with this provision, paragraph (d)(5)(i) requires that negative pressure be maintained in AFB isolation rooms or areas. The purpose of this provision is to prevent the escape of aerosolized *M. tuberculosis* from a room and into the corridors and other areas of the facility where unprotected employees may be exposed. In order for air to flow from one area to another, there must be a difference in the pressure between the two areas. Air will flow from the higher pressure to the lower pressure area. The lower pressure area is at ''negative pressure'' relative to the higher pressure area. The level of negative pressure achieved will depend on the physical configuration of the area, including the air flow path and flow openings. A pressure differential of 0.001 inch of water and an inward air velocity of 100 feet per minute (fpm) are minimum acceptable levels. The pressure difference necessary to achieve and maintain negative pressure in a room is very small and may be difficult to measure accurately. Negative pressure can be achieved by balancing the room supply and exhaust flows to set the exhaust flow to a value of 10% [but no less than 50 cubic feet per minute (cfm)] greater than the supply (Ex. 4B).

As stated above, the negative pressure principle plays an important role in controlling the spread of *M. tuberculosis* to other areas of the facility where unprotected workers may be exposed. In isolation rooms and areas, and in areas where high hazard procedures (including autopsies) are performed, engineering controls creating negative pressure will prevent the escape of droplet nuclei from the room, thus preventing dispersion of *M. tuberculosis* into the corridor and other areas of the facility where unprotected employees may be working.

In addition, negative pressure fulfills the secondary purpose of general ventilation by reducing the concentration of contaminants in the air. General ventilation maintains air quality by two processes, dilution and removal of airborne contaminants. Dilution reduces the concentration of contaminants in a room by supplying air that does not contain those contaminants. The supply air mixes with and then displaces some of the contaminated room air, which is subsequently removed from the room by the exhaust system. This process reduces the concentration of droplet nuclei in the room air and the risk of TB transmission.

OSHA is not proposing to allow the use of ultraviolet germicidal irradiation (UVGI) in place of ventilation for controlling aerosolized *M. tuberculosis.* Although the germicidal properties of certain wavelengths of ultraviolet light (UV–C) are generally recognized, the Agency has not included UVGI as a primary engineering control in the proposed standard. With regard to the use of UVGI, CDC states:

> Because the clinical effectiveness of UV systems varies, and because of the risk for transmission of *M. tuberculosis* if a system malfunctions or is maintained improperly, UVGI is not recommended for the following specific applications: 1. Duct systems using UVGI are not recommended as a substitute for HEPA filters if air from isolation rooms must be recirculated to other areas of a facility. 2. UVGI alone is not recommended as a substitute for HEPA filtration or local exhaust of air to the outside from booths, tents, or hoods used for cough-inducing procedures. 3. UVGI is not a substitute for negative pressure. (Ex. 4B)

The CDC goes on to discuss a number of factors that affect the effectiveness of UVGI and UV lamps in killing airborne tubercle bacilli. These factors include the intensity of UVGI, the duration of irradiation of the organism, the relative humidity of the environment, the age of the UV lamp, and the amount of dust on the lamp's surface (Ex. 4B). In light of this information, the Agency does not believe that UVGI can reliably and uniformly control airborne tubercle bacilli. Consequently, UVGI is not acceptable as a primary engineering control. However, some employers may choose to use UVGI as a supplement to ventilation or HEPA filtration. In recognition of this, OSHA has included information regarding UVGI safety and health concerns in Appendix D of this section.

Paragraph (d)(5)(ii) requires that in those areas where negative pressure is required (i.e., AFB isolation rooms or areas), maintenance of negative pressure must be qualitatively demonstrated (e.g., by smoke trails) daily while in use for tuberculosis isolation. In Supplement 3 of its 1994 guidelines, CDC states:

> TB isolation rooms should be checked daily for negative pressure while being used for TB isolation. (Ex. 4B)

The principle and advantages of negative pressure have been discussed above. Proper maintenance of negative pressure will prevent the contaminated air from escaping from the room or area and exposing unprotected employees. One means of qualitatively demonstrating negative pressure is through the use of smoke trail testing (see Appendix G of this section). Other methods include flutter strips or continuous monitoring devices. With regard to the safety and effectiveness of these methods, the CDC states:

> The concern over the use of smoke tubes is unfounded. Controlled tests by NIOSH have shown that the quantity of smoke that is released is so minute that it is not measurable in the air. The location of the patient and the length of time the patient is exposed dilute the smoke to several orders of magnitude below an 8-hour exposure limit. It is not practical and often not effective to use flutter strips or continuous monitoring devices as alternatives to indicate directional air movement. The air flow (due usually to the small clearance area under the door) is insufficient to move the flutter strip. Likewise, low negative pressure, which will satisfactorily provide adequate directional air flow into the isolation room, may not be readable on continuous monitoring devices. Devices must be capable of reading 0.001 inch of water, the established minimum, to be effective. (Ex. 4B)

In light of this information, employers should be aware that when choosing a method other than smoke trails to demonstrate maintenance of negative pressure, the method chosen should be

reviewed carefully in order to assure that the intended test can be effectively conducted.

Paragraph (d)(5)(iii) stipulates that engineering controls must be maintained, and inspected and performance monitored for filter loading and leakage every six months, whenever filters are changed, and more often if necessary to maintain effectiveness. The primary intent of this provision is to assure that engineering controls are maintained in such a manner that they continue to function effectively. As discussed previously, a number of factors can affect the functioning of engineering controls, such as frozen bearings, broken belts, and burned out motors. It is the employer's responsibility to maintain engineering controls in proper working condition. That is, if a belt breaks on a fan motor, it is not appropriate to delay repairs until the six-month inspection. This provision does, however, stipulate a maximum time period of six months between inspections and performance monitoring of engineering controls and HEPA filters in air systems carrying air that may reasonably be anticipated to contain aerosolized *M. tuberculosis.* The employer's maintenance schedule may specify more frequent inspection, maintenance, and performance monitoring based upon conditions found in that particular work site. For example, the employer, being more familiar with his or her own work setting, may have knowledge that the work environment is very dusty, thus necessitating a more frequent period for changing the filters. When filters are changed, performance monitoring must be conducted to assure that the filter has been correctly installed and is functioning properly. In view of the importance of these systems in reducing the concentration of droplet nuclei and thereby the risk of TB transmission, OSHA believes that six months is the longest period that these systems should be allowed to operate without inspection and performance monitoring. This maximum six-month period of time between consecutive inspections and performance monitoring of HEPA filters is supported by CDC (Ex. 4B).

Paragraph (d)(5)(iv) requires that air from AFB isolation rooms or areas must be exhausted directly outside, away from intake vents and employees. If the air from these areas cannot be exhausted in such a manner or must be recirculated, it must pass through HEPA filters before discharge or recirculation.

In order for the air to be safely discharged, exhaust ducts must not be located near areas that may be populated (e.g., sidewalks or windows that may be opened). In addition, ventilation system exhaust discharges must be designed to prevent re-entry of exhaust air. Wind blowing over a building creates a highly turbulent recirculation zone, which can cause re-entry of the exhaust into the building. Exhaust flow needs to be discharged above the zone. When exhaust air cannot be safely discharged, it must pass through HEPA filters to remove droplet nuclei, thereby precluding re-entry of potentially contaminated air or exposure of individuals who may have to pass through the exhaust airstream. The employer should be aware that exhausting of this air may also fall under federal, state and local regulations concerning environmental discharges.

This provision also states that if a portion of this air is recirculated, it must pass through a properly designed, installed, and maintained HEPA filter before discharge back into general facility ventilation. HEPA filters clean air through the physical removal of particulates from the airstream. These filters have a minimum removal efficiency of 99.97% for particles ≥ 0.3 microns in diameter. Droplet nuclei of *M. tuberculosis* range in size from 1 micron to 5 microns in diameter. Therefore, HEPA filtration can be expected to remove most droplet nuclei from the air. It should be noted that whenever feasible, exhaust air from the AFB isolation rooms or areas must be exhausted to the outside. In its 1994 guidelines, CDC states:

> Air from TB isolation rooms and treatment rooms used to treat patients who have confirmed or suspected infectious TB should be exhausted to the outside in accordance with applicable Federal, state, and local regulations. The air should not be recirculated into the general ventilation. In some instances, recirculation of air into the general ventilation system from such rooms is unavoidable (i.e., in existing facilities in which the ventilation system or facility configuration makes venting the exhaust to the outside impossible). In such cases, HEPA filters should be installed on the exhaust duct leading from the room to the general ventilation system to remove infectious organisms and particulates the size of droplet nuclei from the air before it is returned to the general ventilation system (Section II.F; Suppl. 3). Air from TB isolation rooms and treatment rooms in new or renovated facilities should not be recirculated into the general ventilation system. (Ex. 4B)

The Agency agrees with CDC that exhaust air should be vented to the outside. However, OSHA recognizes that there may be instances where outside discharge may not be feasible and has, therefore, permitted recirculation with HEPA filtration of the recirculated air, in such instances.

Paragraph (d)(5)(v) states that ducts carrying air that may reasonably be anticipated to contain aerosolized *M. tuberculosis* must be maintained under negative pressure for their entire length before in-duct HEPA filtration or until the ducts exit the building for discharge. Ducts maintained under negative pressure will contain exhaust air within the system. Air will not escape to the outside as it would under positive pressure even if there are leaks in the ducts. The purpose of this provision is to prevent escape of air that may contain aerosolized *M. tuberculosis* into areas where occupational exposure is not anticipated and unprotected employees may be exposed.

Paragraph (d)(5)(vi) requires that, while in use for TB isolation, doors and windows of AFB isolation rooms or areas must be kept closed except when doors are opened for the purpose of entering or exiting and when windows are part of the ventilation system being used to achieve negative pressure. For example, the window may be serving as the exit for the exhaust from an in-room HEPA filtration unit. As stated above, AFB isolation rooms and areas are to be maintained under negative pressure while in use for TB isolation. Negative pressure in a room can be altered by small changes in the ventilation system operation, or by the opening and closing of the isolation room doors or windows. In order to assure that the ventilation system functions as intended, it is essential that, once an operating configuration has been established, doors and windows be opened only when necessary.

Paragraph (d)(5)(vii) stipulates that when an AFB isolation room or area is vacated by an individual with suspected or confirmed infectious TB, the room or area must be ventilated for an appropriate period of time, according to current CDC recommendations for a removal efficiency of 99.9%, before permitting employees to enter without respiratory protection (see Appendix C of this section). The time required for removing airborne particles from an enclosed space depends on several factors. These include the number of air changes per hour (which is determined, in part, by the number of cubic feet of air in the room or booth), the rate at which air is entering the room or booth at the intake source versus the rate at which it is being exhausted, the location of the ventilation inlet and outlet, and the physical configuration of the room or booth. The times needed to achieve a given removal efficiency (i.e., 90%, 99%, and 99.9%) presented in

Appendix C of this section assume perfect air mixing within a space. However, perfect mixing of air normally does not occur because a number of factors, such as room configuration, may influence the movement of air. Because perfect air mixing is not likely to occur, the necessary time required for a specific removal efficiency, as presented in Appendix C of this section, may be underestimated. In order to compensate for this shortcoming, OSHA has proposed that the most conservative (i.e., protective) removal efficiency, i.e., 99.9%, be used to determine the appropriate amount of time an AFB isolation room or area must be ventilated before permitting employees to enter without respiratory protection. Using this conservative approach will help to assure that an appropriate time has passed before unprotected employees enter the area, even in situations where perfect air mixing has not occurred. Ventilation of the room would not be necessary if the room was previously occupied by an individual with suspected infectious tuberculosis and that individual was medically determined to be noninfectious, since there would be no droplet nuclei present.

Paragraph (d)(6) requires that the employer must inform any outside contractor who provides temporary or contract employees who may incur occupational exposure of the hazard, so that the contractor can institute precautions to protect his or her employees. OSHA is concerned that the contractor be aware of the existence of TB hazards so that appropriate actions can be undertaken to prevent the contractor's employees from being unwittingly exposed. By conveying such information to the contractor, accountability for these employees is established. If the contractor is aware of the hazards, then it is the responsibility of the contractor to institute procedures to protect his or her employees from occupational exposure to *M. tuberculosis*.

Paragraph (e) Clinical and Research Laboratories

This paragraph addresses requirements that must be met by clinical and research laboratories engaged in the culture, production, concentration, experimentation, and manipulation of *M. tuberculosis*. These requirements apply in addition to the other requirements of the standard.

The risks associated with direct and routine work with pathogens have long been recognized:

> Microbiology laboratories are special, often unique, work environments that may pose special infectious disease risks to persons in or near them. Personnel have contracted infections in the laboratory throughout the history of microbiology. (Ex. 7–72)

Clinical and research laboratories working with *M. tuberculosis* are no exception, and the risks associated with work in such facilities warrant additional protective measures.

Prior to 1984, no single code of practice, standards, guidelines or other publication providing detailed descriptions of techniques or equipment for laboratory activities involving pathogens was available. In that year, the CDC and the National Institutes of Health (NIH) published guidelines entitled ''Biosafety in Microbiological and Biomedical Laboratories''. These biosafety guidelines were based on combinations of standard and special practices, equipment, and facilities recommended for use when working with various infectious agents in laboratory settings. The most current revision of these guidelines is dated 1993. (Ex. 7–72)

The biosafety guidelines are not limited to *M. tuberculosis*, which is the subject of this standard. They are applicable to work with any infectious agent. The basic format for the biosafety guidelines categorizes infectious agents and laboratory activities into four classes or levels denoted as Biosafety Levels 1 through 4. These biosafety levels (BSL) are comprised of combinations of laboratory practices and techniques, safety equipment, and laboratory facilities appropriate for the operations performed and the hazard posed. The Guidelines indicate the BSL to be used when working with various infectious agents and infected animals.

There is a risk to employees working with materials containing *M. tuberculosis*. When the concentration of this bacterium is increased as the result of growing it in cell culture or through artificial concentration, then the risk of transmission to employees increases if the bacteria are not contained. Therefore, the proposed standard requires the employer to implement a number of provisions specifically related to these laboratory work settings.

The requirements in paragraph (e), including those regarding biosafety cabinets, are derived primarily from the CDC/NIH recommendations found in ''Biosafety in Microbiological and Biomedical Laboratories'' (Ex. 7–72). Only those provisions that relate to the health and safety of employees are required by the standard. The provisions in paragraph (e) are a minimal program, and OSHA anticipates that employers affected by this paragraph will continue to follow any other appropriate portions of the above recommendations in addition to the requirements of this standard. In addition, the employer is responsible for following this entire standard (e.g. training employees, medical surveillance).

Paragraph (e) applies to two types of facilities that OSHA has designated as ''clinical laboratories'' and ''research laboratories.'' For the purpose of this standard a clinical laboratory is a laboratory or area of a facility that conducts routine and repetitive operations for the diagnosis of TB, such as preparing acid-fast smears and culturing sputa or other clinical specimens for identification, typing or susceptibility testing. A research laboratory is a laboratory that propagates and manipulates cultures of *M. tuberculosis* in large volumes or high concentrations that exceed those used for the identification and typing activities common to clinical laboratories.

The proposed standard requires, in paragraphs (e)(2)(i)(A) through (D), that both clinical and research laboratories follow several standard microbiological practices. All procedures are to be performed in a manner that minimizes the creation of aerosols. In view of the mode of transmission of *M. tuberculosis*, that is, through inhalation of airborne organisms, this provision is extremely important in eliminating or minimizing employee exposure. It is the responsibility of the employer to evaluate laboratory tasks and institute the measures necessary to minimize the creation of aerosols.

OSHA also proposes to adopt the good laboratory and infection control practice of prohibiting pipetting or suctioning by mouth. The use of cotton plugs or other barriers does little to reduce the hazards of mouth pipetting. Even a technician who is skilled in mouth pipetting may inadvertently suck fluids containing *M. tuberculosis* into the mouth. In addition to producing *M. tuberculosis*-containing aerosols when the fluid is expelled, these fluids may also contain bloodborne pathogens that would have contacted the employee's mucous membranes (i.e., the mouth) as well as any blisters, cuts, or other lesions in the mouth or on the lips.

Work surfaces and laboratory equipment must be decontaminated at the end of each shift and after any spill of viable material. This is recognized as good laboratory practice in minimizing the spread of contamination.

Finally, the proposed standard requires that all cultures, stocks, and other wastes contaminated with *M. tuberculosis* be decontaminated before

disposal by a decontamination method, such as autoclaving, known to effectively destroy *M. tuberculosis*. Materials to be decontaminated outside of the immediate laboratory are to be placed in a durable leakproof container, closed to prevent leakage for transport from the laboratory, and labeled or color coded in accordance with paragraph (h)(1)(ii) of this section. Decontamination before disposal helps assure that other employees are not inadvertently exposed to the bacterium.

Although the proposed standard requires proper containerization of laboratory wastes, it includes no such requirement for wastes originating from the provision of care or services to individuals with suspected or confirmed infectious TB (e.g., facial tissues that the individual has used). The reason for this is that items, such as facial tissues, capture and contain the liquids generated by the individual. Once captured, the liquid is not readily aerosolized. In their guidelines, the CDC states:

> Disposable items contaminated with respiratory secretions are not associated with transmission of *M. tuberculosis*. (Ex. 4B)

In the laboratory, however, the liquids containing *M. tuberculosis* are generally not captured or contained on an item but exist as an individual specimen or culture. Also, in some instances, the bacilli have been concentrated. The possibility, therefore, for formation of droplet nuclei from these wastes is increased. Consequently, it is necessary to properly containerize and label laboratory wastes to assist in preventing droplet nuclei formation and possible infection. Proper containerization and labeling of wastes to be decontaminated outside a laboratory not only help prevent employee exposure but also warn employees who come in contact with this waste of the hazard within the container.

Paragraphs (e)(2)(ii)(A) through (E) describe special practices to be followed in clinical and research laboratories, such as limiting access to the laboratory to authorized personnel, preparing and maintaining a biosafety manual, properly containerizing materials contaminated with *M. tuberculosis*, immediately containerizing and cleaning up all spills potentially contaminated with *M. tuberculosis*, and posting a sign with the universal biohazard symbol on access doors when materials containing or animals infected with *M. tuberculosis* are present. Limiting access to these laboratories assures that unauthorized individuals are not placed at risk, and that they do not distract or otherwise interfere with the activity of the authorized employees. This provision works in concert with the requirement for signs in paragraph (h)(2)(iv) and ensures that only employees who meet the special requirements set forth by the laboratory director, which will include training, personal protective equipment, and other requirements, could enter the area.

The requirement for a biosafety manual helps assure that any additional procedures are developed to address situations that are unique to a particular facility and to provide appropriate protection to exposed employees. The manual must be reviewed as necessary and at least annually. The manual must also be updated as necessary to reflect changes in the work setting. The phrase ''as necessary'' has been used to indicate that updating of the manual to reflect work setting changes is to be done as soon as possible and is not to be postponed until the annual review. Employees are required to read the biosafety manual's sections on potential hazards and practices and procedures.

The requirement that contaminated material removed from the work area be placed in a container that prevents leakage during collection, handling, processing, storage, transport, or shipping is to assure that there are no accidental spills or other contamination that may place other employees at risk.

Paragraph (e)(2)(ii)(D) requires that spills be cleaned up immediately by employees trained and equipped to work with potentially concentrated *M. tuberculosis*. Because *M. tuberculosis* can become aerosolized during cleanup procedures, the task cannot be done by someone who is not skilled and properly equipped. In addition, exposure incidents must be reported so that the post-exposure management and follow-up required by paragraph (g) can be initiated and the circumstances surrounding the exposure incidents can be investigated.

Paragraph (e)(2)(ii)(E) requires that, when materials or animals infected with *M. tuberculosis* are present in the laboratory, a hazard warning sign, in accordance with paragraph (h)(2)(iv) of Communication of Hazards and Training, incorporating the universal biohazard symbol, shall be posted on all laboratory and animal room access doors. Because *M. tuberculosis* is present in the materials listed above, it is necessary to warn individuals who may enter this area of the hazards that are present so that they can take proper precautions to guard themselves against exposure.

The requirements of paragraph (e)(2)(iii)(A) stipulate that whenever activities with the potential for generating aerosols of *M. tuberculosis* are conducted, and whenever high concentrations or volumes of *M. tuberculosis* are used, a certified Class 2 biological safety cabinet must be used. Such materials may be centrifuged in the open laboratory, i.e., outside of a biosafety cabinet, if sealed rotor heads or centrifuge safety cups are used. These requirements protect employees from exposure during the performance of procedures by assuring that aerosolized *M. tuberculosis* will be contained and kept away from the worker's breathing zone.

Paragraph (e)(2)(iii)(B) requires that biological safety cabinets shall be certified when they are installed, annually thereafter, whenever they are moved, and whenever filters are changed. Biological safety cabinets must be certified to ensure that they will provide the proper protection. The National Sanitation Foundation (NSF) Standard 49 describes design, construction, and performance criteria for biosafety cabinets. (Ex. 7–135) Moreover, this NSF standard is subject to periodic review by the NSF in order to keep the requirements consistent with new technology. OSHA has incorporated the current NSF Standard 49 performance criteria into the OSHA standard. For example, Standard 49 states:

> * * * that each cabinet be tested and performance evaluated on site, assuring that all physical containment criteria are met at the time of installation, prior to use, and periodically thereafter. (Ex. 7–135)

NSF Standard 49 also calls for recertification of cabinets at least annually, when HEPA filters are changed, and after maintenance repairs or relocation of a cabinet. Therefore, OSHA believes that the requirements in the proposed standard are appropriate and that cabinets that are certified by the manufacturer as Class 2 or 3 will provide adequate protection to employees.

Paragraph (e)(2)(iv) requires that a method for decontamination of wastes contaminated with *M. tuberculosis* (e.g., autoclave, chemical disinfection, incinerator, or other approved decontamination system known to effectively destroy *M. tuberculosis*) must be available within or as near as feasible to the work area. The availability of such methods of decontamination is required for inactivating or destroying *M. tuberculosis* in or on a variety of media, including culture fluids, plastic ware, and equipment. These materials must be decontaminated to prevent potential aerosolization of *M.*

tuberculosis and inadvertent exposure of employees outside of the laboratory.

Research laboratories working with *M. tuberculosis* are held to several additional requirements. Paragraph (e)(3)(i)(A) requires that research facilities keep laboratory doors closed when working with *M. tuberculosis*. Paragraph (e)(3)(i)(B) requires that access to the work area be limited to persons who comply with specified entry and exit requirements. These provisions are adopted from the CDC/NIH recommendations for ''Biosafety in Microbiological and Biomedical Laboratories'' (Ex. 7–72). In addition, paragraph (e)(3)(i)(C) requires that respiratory protection shall be worn in research laboratories when aerosols cannot be safely contained (e.g., when aerosols are generated outside a biological safety cabinet). As stated previously, research laboratories are working with larger volumes and higher concentrations of *M. tuberculosis* than clinical laboratories. As such, the risk to employees from aerosolized bacilli is increased, necessitating that these employees be protected whenever lapses in containment occur. An example of when aerosols would be generated would be when a flask containing *M. tuberculosis* is dropped and broken outside of the biosafety cabinet. Another example would be centrifugation of *M. tuberculosis*-containing cultures in an open centrifuge without aerosol-proof centrifuge safety containers, or utilizing such containers but then opening them outside of the biosafety cabinet (Ex. 7–134).

Paragraph (e)(3)(ii) requires employers to ensure that employees manipulating cultures and clinical or environmental materials that may generate *M. tuberculosis*-containing aerosols, challenging animals with *M. tuberculosis* aerosols, harvesting tissues or fluids from infected animals, or performing necropsies on infected animals use the appropriate containment equipment and/or devices when performing these activities. Such equipment and devices include Class 2 or 3 biosafety cabinets, or appropriate combinations of personal protective equipment and physical containment devices (such as respirators, centrifuge safety cups, sealed centrifuge rotors, and containment caging for animals). This requirement, like the others in this paragraph, is intended to ensure that employees are protected during the performance of these potentially high-hazard procedures.

Research laboratories are also held to additional requirements with regard to facility construction. Paragraph (e)(3)(iii)(A) requires that the laboratory be separated from areas that are open to unrestricted traffic flow within the building. Passage through two sets of self-closing doors is the requirement for entry into the work area from access corridors or other contiguous areas. This type of entrance reduces the likelihood of untrained employees accidentally entering the work area, since such entry necessitates deliberate action on the part of the individual.

Paragraph (e)(3)(iii)(B) requires that windows in the laboratory be closed and sealed. This helps assure containment of any aerosols and helps maintain proper operation of biosafety cabinets through minimization of cross drafts.

Paragraph (e)(3)(iii)(C) requires that a ducted exhaust air ventilation system shall be provided which creates directional airflow that draws air from clean areas into the laboratory toward contaminated areas. The proper direction of the airflow shall be verified (i.e., into the work area) by the employer at least every six months. The exhaust air shall not be recirculated to any other area of the building, shall be discharged to the outside, and shall be dispersed away from occupied areas and air intakes. The requirement that research laboratories have verified directional airflow into the work area is to assure that air is drawn into the laboratory toward contaminated areas to assist in maintaining containment of aerosols within the laboratory.

Paragraph (e)(3)(iii)(D) requires that the HEPA-filtered exhaust from Class 2 or 3 biosafety cabinets is to be discharged to the outside of the building or through the building exhaust system. If it is discharged through the building exhaust system, it must be connected to this system in a manner that avoids any interference with the air balance of the cabinets or the building exhaust system. This is required to assure that biosafety cabinets and the building exhaust system continue to function as intended.

Paragraph (e)(3)(iii)(E) requires that continuous flow centrifuges or other equipment that may produce aerosols must be contained in devices that exhaust air through a HEPA filter before discharge into the laboratory. This assures that any aerosols which may contain *M. tuberculosis* are effectively filtered from the exhaust air before discharge into the laboratory, thereby protecting employees against inadvertent exposure.

All of the requirements discussed above were derived directly from the CDC/NIH's ''Biosafety in Microbiological and Biomedical Laboratories.'' OSHA requests comment on the applicability and OSHA's application of CDC/NIH's guidelines for their use in laboratories which handle *M. tuberculosis*.

Paragraph (f) Respiratory Protection

Respirators serve as supplemental protection to reduce employee exposures when engineering and work practice controls are not sufficient to provide adequate protection against airborne contaminants.

At the opening of the public hearings for the revision of OSHA's General Industry Respiratory Standard, 29 CFR 1910.134, the Agency stated that all aspects of respirator use for protection against tuberculosis would be addressed in the rulemaking for Occupational Exposure to Tuberculosis. Consequently, the respiratory protection portion of this proposal contains all of the respiratory protection provisions that have been preliminarily determined to be applicable to respirator use for TB. In the past, OSHA standards have referred to the Respirator Standard (29 CFR 1910.134) for the general requirements for respirator use (e.g., written respiratory protection program; respirator maintenance) and have included only the respirator provisions specific to the hazard addressed by the standard. OSHA's approach in this proposal, however, is to include provisions relative to all aspects of respirator use for tuberculosis. This will provide interested parties with the opportunity to review and comment on these aspects. To assure consistency across OSHA respiratory protection standards, however, OSHA is considering including in the final TB rule cross-referencing to the general requirements of the Respiratory Protection Standard (29 CFR 1910.134) and retaining in the final TB rule only those provisions specific to respirator use for TB. OSHA seeks comment on this intended approach in the final standard for TB.

Paragraph (f)(1)(i) states that each employer must provide a respirator to each employee who: (A) enters an AFB isolation room or area in use for TB isolation; (B) is present during performance of procedures or services for an individual with suspected or confirmed infectious TB who is not masked; (C) transports an individual with suspected or confirmed infectious TB in an enclosed vehicle or who transports an individual with suspected or confirmed infectious TB within the facility whenever that individual is not masked; (D) repairs, replaces, or maintains air systems or equipment that may reasonably be anticipated to contain aerosolized *M. tuberculosis*; (E)

is working in an area where an unmasked individual with suspected or confirmed infectious TB has been segregated or otherwise confined (e.g., while awaiting transfer), and (F) is working in a residence where an individual with suspected or confirmed infectious TB is known to be present. In addition, paragraph (f)(1)(ii) requires that each employer who operates a research laboratory provide a respirator to each employee who is present when aerosols of *M. tuberculosis* cannot be safely contained.

In discussing the use of respiratory protection in their guidelines, CDC states:

> Personal respiratory protection should be used by (a) persons entering rooms where patients with known or suspected infectious TB are being isolated, (b) persons present during cough-inducing or aerosol-generating procedures performed on such patients, and (c) persons in other settings where administrative and engineering controls are not likely to protect them from inhaling infectious airborne droplet nuclei. These other settings include transporting patients who may have infectious TB in emergency transport vehicles and providing urgent surgical or dental care to patients who may have infectious TB before a determination has been made that the patient is noninfectious. (Ex. 4B)

The guidelines also state that respiratory protection should be worn by personnel who are performing maintenance and testing procedures on HEPA filtration systems (Ex. 4B). Furthermore, the CDC/NIH document ''Biosafety in Microbiological and Biomedical Laboratories'' recommends that respiratory protection be worn whenever aerosols of organisms such as *M. tuberculosis* cannot be safely contained (Ex. 7–72). Consequently, employees who may need to wear respirators could include not only health care providers but also employees such as housekeepers, dietary personnel, laboratory technicians, employees in intake areas, maintenance personnel, social workers, and so forth. It is the employer's responsibility to determine which occupationally exposed employees would be covered under this provision and, therefore, would need to wear a respirator.

With regard to utilization of respiratory protection when entering an AFB isolation room or area, the reader is referred to the definition of ''AFB isolation room or area'' in paragraph (j), Definitions. This definition clarifies that the requirement refers not only to situations such as entering a patient room occupied by an individual with suspected or confirmed infectious TB but also refers to entering any area where high-hazard procedures are being performed and entering an autopsy room where *M. tuberculosis* may be aerosolized.

Paragraph (f)(1)(i)(B) requires respirator use when an employee is present during performance of procedures or services for an unmasked individual with suspected or confirmed infectious TB. This provision is intended to cover those situations in which a procedure or service is performed outside of an AFB isolation room or area. For example, a facility may not have a portable X-ray and may, therefore, perform this procedure in a standard X-ray room. If the individual is not masked in such a situation, all employees present (i.e., the X-ray technician and any other employees in the room) must utilize respiratory protection.

As stated previously under discussion of Scope, employees rendering emergency medical services may spend time in very close proximity to individuals with suspected or confirmed infectious TB within an enclosed vehicle. Even though the individual may be masked, droplet nuclei that escape capture in the mask are contained within the vehicle, thereby increasing the likelihood that employees will breathe droplet nuclei generated when the patient coughs or speaks. In addition, under paragraph (f)(1)(i)(D), employees who repair, replace, on maintain air systems or equipment that may reasonably be anticipated to contain aerosolized *M. tuberculosis* are at risk of occupational exposure as a result of exposure to air that could contain aerosolized bacilli. Therefore, respirator use would be required in this situation.

As discussed under Scope, aerosolized *M. tuberculosis* is a recognized hazard to laboratory personnel. When aerosols of *M. tuberculosis* cannot be safely contained, such as during a spill, the employer is required to provide a respirator to each employee who is present during this time. This is consistent with CDC/NIH recommendations regarding respirator use in research laboratories (Ex. 7–72).

Unlike some other airborne contaminants, the quantity of *M. tuberculosis* that, when inhaled, will result in infection (i.e., infectious dose) has not been determined conclusively. The number of droplet nuclei expelled into a room by an infectious individual or aerosol-producing procedure and the concentration of droplet nuclei in a room or area are unknown. Consequently, there is no basis to judge the effectiveness of other control measures present even though they may be operating as intended. OSHA therefore agrees with the CDC that, in the above situations, other controls that may be in place cannot be assumed to adequately protect employees against exposure to airborne TB droplet nuclei and therefore that the use of respiratory protection is necessary.

While OSHA agrees with and has adopted most of the CDC's recommendations regarding when respiratory protection is necessary, the Agency has extended respirator use to two additional situations. More specifically, when an individual with suspected or confirmed infectious TB is not masked and is transported within a facility, the employee transporting the individual must wear a respirator. While CDC recommends masking individuals with suspected or confirmed infectious TB prior to transporting them, there may be special circumstances in which the individual may not be masked (e.g., individual is combative and will not wear a mask). The employee transporting the individual would most likely spend an extended period of time in close proximity to the individual, either walking beside or behind (e.g., pushing a wheelchair) the individual. The employee would, therefore, be walking directly through the airspace into which the individual would be expelling droplet nuclei, receiving exposure each time the individual coughed, resulting in multiple relatively concentrated exposures. In view of this, the latter portion of paragraph (f)(1)(i)(C) addresses the Agency's belief that it is necessary and justified that respiratory protection be worn by the employee to protect against occupational exposure if the individual is not masked.

The second situation, under paragraph (f)(1)(i)(E), requires respirator use by an employee when working in an area where an unmasked individual with suspected or confirmed infectious TB has been segregated or otherwise confined, for example while awaiting transfer. As discussed above, it is assumed that such individuals would normally be masked. Here again, however, there may be circumstances that preclude the individual from being masked (e.g., the individual is combative). Therefore, employees who must work in the area where these unmasked individuals are located, whether working directly with the individual or performing other duties, must wear a respirator to protect against possible tuberculosis infection.

Paragraph (f)(1)(i)(F) requires that a respirator be worn by an employee who is working in a residence where an individual with suspected or confirmed

infectious TB is known to be present. In this situation, whether the individual is masked or unmasked does not trigger respirator use since the individual has been releasing droplet nuclei into the residence airspace. The CDC refers to this type of situation in its discussion of the provision of home health care and states:

> Health care workers who provide medical services in the homes of patients who have suspected or confirmed infectious TB should instruct such patients to cover their mouths and noses with a tissue when coughing or sneezing. Until such patients are no longer infectious, HCWs should wear respiratory protection when entering these patients' homes. (Ex. 4B)

In addition to home health care and home-based hospice care workers, other employees, such as social workers who are entering these residences, would come under this provision. It is the Agency's intent that a respirator be used by an employee in these situations for the time that the employee is in the residence and that respirator use continue until the individual is noninfectious.

The proposed standard, in paragraphs (f)(1)(iii) and (f)(1)(iv), places several general responsibilities upon the employer regarding respiratory protection. Paragraph (f)(1)(iii) states that where respirators are required by the standard, the employer shall provide them at no cost to the employee and assure that they are used in accordance with the requirements of the standard. Paragraph (f)(1)(iv) stipulates further that the employer must assure that the employee dons a respirator before entering the work settings or performing the tasks set forth in paragraphs (f)(1)i and (f)(1)(ii) above and uses it until leaving the work setting or completing the task, regardless of other control measures in place.

It has been OSHA's long-standing policy to hold the employer responsible for controlling exposure to hazards in his or her workplace and to fulfill this responsibility at no cost to the employee. Therefore, the financial burden for purchasing and providing personal protective equipment, including respirators, rests upon the employer just as it does for all other control measures (e.g., engineering controls). OSHA believes that in order to assure that employees are adequately protected, the employer has the responsibility not only to provide respiratory protection, but also to assure that it is utilized when necessary. Furthermore, respiratory protection must be donned prior to entering the above work settings or performing the tasks, for the period of time that the employee remains in these work settings, and must not be removed until the employee leaves the work setting or completes the tasks. In this way, the employee is protected for the entire period of occupational exposure.

It is not OSHA's intent that each employee be monitored constantly for compliance; however, the Agency does believe that the employer has the power to assure that employees follow specific rules. For example, most employers have requirements that they require employees to follow, such as reporting to work on time, working a minimum number of hours per day, notifying the employer when the individual is unable to report for work, and taking certain precautions to prevent nosocomial infections. Following these requirements is not left to the employee's discretion, and employers generally have some process to ensure conformance with these procedures. Therefore, the Agency believes that the employer has not only the responsibility, but also the ability, to assure that respiratory protection is used in accordance with the requirements of this section.

Paragraph (f)(2)(i) requires that each employer who has any employee whose occupational exposure is based on entering any of the work settings or performing any of the tasks described in paragraph (f)(1) must establish and implement a written respiratory protection program that assures that respirators are properly selected, fitted, used, and maintained. The program must include the following elements: (A) Procedures for selecting respirators for use in the work setting; (B) a determination of each employee's ability to wear a respirator, as required under paragraph (g)(3)(ii), Medical Surveillance, for each employee required to wear a respirator; (C) procedures for the proper use of respirators; (D) fit testing procedures for tight-fitting respirators; (E) procedures and schedules for cleaning, disinfecting, storing, inspecting, repairing, or otherwise maintaining respirators; (F) training of employees to assure the proper use and maintenance of the respirators as required under paragraph (h), Communication of Hazards and Training; and (G) procedures for periodically evaluating the effectiveness of the program. Written standard operating procedures are essential to an effective respiratory protection program. Developing and writing down standard operating procedures require employers to think through how all of the requirements pertaining to respirators will be met in their workplace. In addition, this provision assures that the employer establishes standardized procedures for selecting, using, and maintaining respirators in the workplace. OSHA's long-standing position has been that a systematic respiratory protection program is necessary to provide for consistency in protection. Guidance that has been developed by an outside party (e.g., a respirator manufacturer) on the general use of a particular respirator would not address the site-specific aspects of the employer's work setting and would not be an appropriate substitute for a respiratory protection program.

Paragraph (f)(2)(ii) requires the employer to designate a person qualified by appropriate training or experience to be responsible for the administration of the respiratory protection program and for conducting the required periodic evaluations of its effectiveness. To assure that the integrity of the respiratory protection program is maintained through the continuous oversight of one responsible individual, OSHA is proposing that a qualified person be designated as responsible for the administration of the program. That individual can work with a committee or assign responsibility for portions of the program to other personnel, but the overall responsibility for the operation of the program remains with the designated person. This approach ensures coordination of all facets of the program. The level of training or experience necessary for a designated person has been left performance oriented since this will vary with the complexity of the respirator program. However, the person chosen would need to have sufficient knowledge of respiratory protection and the workplace to properly supervise the program.

Employers are required, in paragraph (f)(2)(iii), to review and update the written program as necessary to reflect current workplace conditions and respirator use. Reviewing and updating will assure that the program addresses current conditions. The reason OSHA has not set a schedule for reviewing the program is because conditions may change frequently in some work settings while remaining relatively stable in others. Thus, the employer determines the frequency of the review. However, when an employer is aware of changes in the workplace or respirator use which could necessitate changes in the written program, it is not appropriate to delay revising the written program. OSHA's use of the phrase ''as necessary'' in the requirement is intended to assure that such changes are incorporated into the written program expeditiously. As the workplace situation or respirator use

changes, the program is to be revised. In addition, paragraph (f)(2)(iv) requires that employers, upon request, make the written respiratory protection program available to affected employees, their designated representatives, the Assistant Secretary, and the Director. This provision also requires that a copy of the program be submitted to the Assistant Secretary and/or the Director, if requested.

Paragraph (f)(3) sets out the respirator characteristics that must be satisfied in order to provide employees with a respirator that will protect them against aerosolized *M. tuberculosis.* These criteria are presented in performance-oriented language to provide flexibility in choice of respirators and have been drawn from CDC recommendations (Ex. 4B). CDC has based these criteria on currently available information relative to respirators that includes:

* * * (a) data on the effectiveness of respiratory protection against noninfectious hazardous material in workplaces other than health-care settings and on an interpretation of how these data can be applied to respiratory protection against *M. tuberculosis*; (b) data on the efficiency of respirator filters in filtering biological aerosols; (c) data on face-seal leakage; and (d) data on the characteristics of respirators that were used in conjunction with administrative and engineering controls in outbreak settings where transmission to HCWs and patients was terminated (Ex. 4B).

The CDC Guidelines go on to state:

Available data suggest that infectious droplet nuclei range in size from 1 [micron] to 5 [microns]; therefore, respirators used in health-care settings should be able to efficiently filter the smallest particle in this range. Fifty liters per minute is a reasonable estimate of the highest airflow rate an HCW is likely to achieve during breathing, even while performing strenuous work activities (Ex. 4B).

In their 1994 TB guidelines, the CDC states:

Respiratory protective devices used in health-care settings for protection against *M. tuberculosis* should meet the following standard performance criteria:

1. The ability to filter particles 1 um in size in the unloaded state with a filter efficiency of ≤ 95% (i.e., filter leakage of ≤ 5%), given flow rates of up to 50 L per minute.
2. The ability to be qualitatively or quantitatively fit tested in a reliable way to obtain a face-seal leakage of ≤ 10%.
3. The ability to fit different facial sizes and characteristics of HCWs [health care workers], which can usually be met by making the respirators available in at least three sizes.
4. The ability to be checked for facepiece fit, in accordance with standards established by the Occupational Safety and Health Administration (OSHA) and good industrial hygiene practice, by HCWs each time they put on their respirators. (Ex. 4B)

The various respirator provisions that OSHA is proposing rely heavily on the CDC's aforementioned respirator performance criteria. The second, third, and fourth CDC criteria are addressed by paragraphs (f)(3)(i) (A) and (B) and paragraph (f)(5)(ii). Paragraph (f)(3)(i) requires the employer to select and provide properly fitted negative pressure or more protective respirators. Negative pressure respirators must be capable of being: (A) Qualitatively or quantitatively fit tested in a reliable way to verify a face-seal leakage of no more than 10%; and (B) fit checked by the employee each time the respirator is donned. Paragraph (f)(5)(ii) requires that employers assure that each employee who must wear a tight-fitting respirator is fit tested and passes the fit test. All of these provisions deal with the ability of the respirator to achieve a good face seal with a particular employee.

Good face fit is critical in assuring proper performance of respiratory protection. When an employee inhales through a respirator that does not fit properly, contaminated workplace air can enter the respirator through gaps and leaks in the seal between the face and the facepiece. OSHA is requiring the employer to provide each employee who must wear a respirator with one that fits. To do so, the employer will have to consider the facial sizes and characteristics in his or her workplace. It is not necessary for the employer to have respirators of different sizes of characteristics unless the employees need them. In other words, an employer may need only one or two styles and sizes. However, in workplaces where employees have different facial sizes and characteristics, obtaining proper respirator fit for each employee may require the fit testing of different mask sizes, possibly from several manufacturers. Proper respirator fit reduces inhalation leakage through the face-to-facepiece seal to a minimum.

Once a respirator has been selected based on its ability to achieve an adequate face-to-facepiece seal, the employee must be able to check that the respirator is properly seated and sealed to his or her face each time it is donned. The respirator, therefore, must be able to be fit checked by the employee. This is a procedure in which the employee covers the filter surface of the respirator and inhales (negative fit check) and exhales (positive fit check). If the respirator has an exhalation valve, this valve must be covered during the positive fit check. A respirator that is properly sealed will firmly adhere to the wearer's face upon inhalation due to the negative pressure created inside the mask. Upon exhalation, the mask should lift slightly off of the wearer's face to allow air to escape around the face seal. Employers should be aware that a problem could exist with fit checking some disposable negative pressure respirators. That is, it is difficult to cover the entire filter surface, thereby hindering the employee's ability to perform a proper fit check. At least one respirator manufacturer has developed a ''fit-check cup'' that covers the filter surface of their disposable respirator, thereby permitting the user to more easily perform a fit check. Reusable elastomeric facepiece respirators utilize filter cartridges that can be covered for performing a fit check.

CDC's first criteria, regarding filter efficiency, is addressed under paragraph (f)(3)(ii) of the standard. This provision requires the employer to select a respirator that will function effectively in the conditions of the work setting. In addition to meeting the criteria in paragraph (f)(3)(i) above, the respirator shall be, at a minimum, either a High Efficiency Particulate Air (HEPA) respirator selected from among those jointly approved as acceptable by the Mine Safety and Health Administration (MSHA) and by the National Institute for Occupational Safety and Health (NIOSH) under the provisions of 30 CFR part 11, or an N95 respirator certified by NIOSH under the provisions of 42 CFR part 84.

NIOSH and MSHA are the government agencies charged with testing and certifying respiratory protective devices. It has always been OSHA's policy that respiratory protection must be certified by these agencies before being deemed acceptable. Until recently, HEPA respirators were the only NIOSH certified negative pressure respirators that met the CDC's filter efficiency criteria. However, on July 10, 1995, NIOSH's original respirator certification procedures for air-purifying particulate respirators, 30 CFR part 11, were replaced by revised procedures, 42 CFR part 84 (Ex. 7–261). Under the new procedures, all nonpowered air-purifying particulate respirators are challenged with a 0.3 micron particle (the most penetrating size) at a flow rate of 85 liters per minute. At the conclusion of the test, those respirators that pass are placed into one of nine classes of filters (three levels of filter efficiency, with three categories of resistance to filter efficiency degradation). The three levels of filter efficiency are 99.97%, 99%, and 95%. The three categories of resistance to filter efficiency degradation are labeled N (not resistant to oil), R (resistant to

oil), and P (oil proof). Given these categories, a type N95 respirator would meet or exceed the filter efficiency performance criteria set forth in the CDC guidelines which state that a respirator appropriate for use in protecting against transmission of tuberculosis must be able to filter particles 1 micron in size in the unloaded state with a filter efficiency of ≥95%, given flow rates up to 50 liters per minute (Ex. 4B). The underlying reasoning for the acceptability of type N95 respirators is that their filter efficiency of 95% for a 0.3 micron particle will exceed 95% filtering efficiency for a particle three times as large (i.e., 1 micron). Also, the Agency assumes that oil aerosols are not likely to be found in the work settings covered by the standard, and therefore, that the use of a category N respirator would be sufficient. However, if oil aerosols are present, the employer would be expected to consider this when selecting the category of respirator to be used in his or her workplace.

OSHA is permitting the employer to select either a HEPA respirator certified under 30 CFR part 11 or a respirator certified under 42 CFR part 84, since particulate respirators certified under both of these regulations are currently on the market. HEPA respirators are the only nonpowered particulate respirators certified under 30 CFR part 11 that meet the CDC guidelines filtration criteria. However, applications for certification of nonpowered particulate respirators under 30 CFR part 11 are no longer being accepted by NIOSH. Therefore, dwindling stocks of HEPA respirators certified under that regulation will eventually lead to their unavailability, and employers will of necessity be selecting respirators from those approved under 42 CFR part 84.

Paragraph (f)(4)(i) states that the employer shall not permit any respirator that depends on a tight face-to-facepiece seal for effectiveness to be worn by employees having any conditions that prevent such a seal. Examples of these conditions include, but are not limited to, facial hair that comes between the sealing surface of the facepiece and the face or facial hair that interferes with valve function, absence of normally worn dentures, facial scars, or headgear that projects under the facepiece seal. Paragraph (f)(4)(ii) requires the employer to assure that each employee who wears corrective glasses or goggles wears them in such a manner that they do not interfere with the seal of the facepiece to the face of the wearer. Tight-fitting facepiece respirators rely on a good face-to-facepiece seal in order to achieve effective protection. Therefore, the employer must not allow employees to wear such respirators with conditions that prevent such a seal. Several studies support the prohibition of facial hair that comes between the sealing surface of the facepiece and the face (Exs. 7–243, 7-242, 7–182). A study by Skretvedt and Loschiavo found that bearded subjects wearing half-mask respirators had a median face seal leakage 246 times greater than clean shaven subjects. They go on to state:

> Even though a number of bearded individuals did obtain fit factors above OSHA's minimum requirement for half-mask respirators, they all failed the qualitative fit test. No relationship was found between the length, shape, density and texture of beards and the amount of face seal leakage. Therefore, the only way to identify bearded negative-pressure respirator wearers obtaining fit factors above OSHA's minimum requirements would be by performing a quantitative fit test on them. However, even if quantitative fit tests are performed on all bearded individuals, another problem must be faced. The drop in the fit factor experienced when a beard is present is of such magnitude that no confidence can be placed in the protection the respirator will provide in the workplace or in future donnings. All respirator users experience variability from one donning to the next. This fit variability from donning to donning occurs due to changes in strap tension, positioning on the face, and a host of other variables. Donning-to-donning fit variability for bearded individuals will be even greater since additional variables will be introduced. A beard is a dynamically changing thing. The hair length constantly changes as well as the orientation of the hair in the sealing surface. Beards also accumulate moisture, natural oils, and debris from the workplace. Even though a percentage of bearded respirator wearers obtain fit factors slightly above OSHA's minimum requirements, the tremendous drop in fit factor resulting from the presence of a beard is such that the safety factor necessary to accommodate the variability of fit no longer exists. In summary, although bearded individuals may be able to achieve fit factors above OSHA's minimum requirements during a specific quantitative fit test, the drop in protection caused by a beard coupled with the large fit variability from donning to donning makes it quite likely that the individual will not obtain the minimum required protection in the workplace. (Ex. 7–243)

Therefore, while a bearded respirator wearer may be able to obtain a satisfactory fit on a particular occasion, one cannot assume that the individual can reliably be expected to achieve that same protection level each time the respirator is used. Beards grow and change daily. Each time a respirator is donned there is fit variability. Such variability in face seal is greatly increased for bearded workers. This large variability in fit means that a reliable seal cannot be reasonably expected. This provision should not be construed as a blanket prohibition on beards among respirator wearers. There are other types of respiratory equipment such as hoods, helmets and suits that can be worn by employees with beards, since they do not rely upon a tight facepiece fit. In addition, this provision refers to facial hair that interferes with the facepiece seal rather than simply growth of beard or sideburns. It is the interference with the facepiece seal that is the concern, not the presence of facial hair. Other conditions such as the absence of normally worn dentures, facial scarring and cosmetic surgery change the geometry of the face, thereby changing the ability of the respirator wearer to achieve a facepiece seal. Facepiece seal may also be compromised when headgear, temple pieces and nose pieces of glasses, the edges of goggles and so forth project underneath the respirator's sealing surface. Both of the above provisions are intended to eliminate or minimize conditions that jeopardize face-to-facepiece seal and could permit leakage of outside air into the facepiece.

Paragraph (f)(4)(iii) states that disposable respirators must be discarded when excessive resistance, physical damage, or any other condition renders the respirator unsuitable for use. It is not expected that the filter media of respiratory protective devices would become occluded with particulates in the work settings covered by this standard. However, if excessive resistance is noted, the respirator must be discarded. Also, such respirators must be structurally sound in order to provide a proper face seal and maintain their effectiveness. Whenever physical damage occurs (e.g., the respirator is crumpled or torn; the flexible face seal is damaged; a head strap is broken), effective functioning cannot be assured and the respirator must be replaced. In addition, other conditions may render the respirator unsuitable for use (e.g., the respirator may become contaminated with blood), thereby requiring discard.

In view of the types of activities carried out and the environmental conditions encountered in the work settings covered by this standard, OSHA is proposing to allow the multiple use of disposable respirators. However, this action should in no way be construed as setting a precedent for the use of disposable respirators in any other OSHA standards or in how OSHA views multiple use of disposable respirators in other work settings. OSHA requests comment on the approach taken in this proposal toward the reuse of disposable respirators.

Paragraph (f)(4)(iv) requires the employer to assure that each employee, upon donning a tight-fitting respirator, performs a facepiece fit check prior to entering a work area where respirators are required. In performing the fit check, the procedures in Appendix B or other procedures recommended by the respirator manufacturer that provide equivalent protection to the procedures in Appendix B must be used. This provision is supported by a recent study by Meyers et al. that concluded:

> * * * for wearers of respirators that have been properly fit by a recognized fit test, conducting fit checks according to the manufacturer's instructions can be a useful tool for more consistently maintaining the quality of respirator donning. (Ex. 7–233)

The use of such seal checks are a way of helping to assure that attention is paid to obtaining an adequate facepiece seal each time a respirator is used.

The standard requires, under paragraph (f)(4)(v), that respirators be immediately repaired, or discarded and replaced when they are no longer in proper working condition. Examples of these changes in condition would be that a strap has broken, the respirator has lost its shape, or the face seal can no longer be maintained. As discussed above, respirators must be in good working condition in order to function effectively. Therefore, it is imperative that they not be used if they have been impaired in any way. The respirator manufacturers can supply replacement parts for damaged portions of their elastomeric respirators. Disposable respirators cannot be repaired and must be discarded when damaged.

Paragraph (f)(4)(vi) stipulates that the employer shall permit each employee to leave the respirator use area as soon as practical to: (A) change the filter elements or replace the respirator whenever the ability of the respirator to function effectively is compromised or the employee detects a change in breathing resistance; or (B) wash his or her face and respirator facepiece as necessary to prevent skin irritation associated with respirator use. This provision encourages and facilitates the proper use of respirators by employees by authorizing employees to take specific actions to assure the effective functioning of their respirators. This provision is consistent with requirements in other health standards (e.g., Lead, 29 CFR 1910.1025; Cadmium, 29 CFR 1910.1027).

Considering the health problems that may be exacerbated with respirator use and their associated detrimental effects on an employee, the proposal states in paragraph (f)(4)(vii) that each employee required to wear a respirator under this section shall be evaluated in accordance with paragraph (g), Medical Surveillance, of this section to determine whether any health conditions exist that could affect the employee's ability to wear a respirator. In addition, paragraph (f)(4)(viii) states that no employee shall be assigned a task requiring the use of a respirator if, based upon the employee's most recent evaluation, the physician or other licensed health care professional, as appropriate, determines that the employee will be unable to continue to function adequately while wearing a respirator. If the physician or other licensed health care professional, as appropriate, determines that the employee's job activities must be limited, or that the employee must be removed from the employee's current job because of the employee's inability to wear a respirator, the limitation or removal shall be in accordance with paragraph (g)(5)(iii) under Medical Removal Protection of this section.

Common health problems that could interfere with respirator use include claustrophobia (an intolerance of feeling enclosed and a subjective feeling of breathing difficulty), chronic rhinitis, nasal allergies that would necessitate frequent removal of the respirator to deal with nasal discharges, and chronic sinusitis. In addition, difficulties with the use of respirators may arise in employees with respiratory or cardiac diseases. Respiratory diseases include chronic obstructive pulmonary disease, emphysema, asthma, and moderate to severe pneumoconiosis. Cardiac or cardiorespiratory diseases that may affect respirator wear include any type of congestive heart disease, other ischemic heart diseases, and hypertension.

As discussed further under paragraph (g)(5)(iv), Medical Surveillance, of this section, employees who are removed from work due to the inability to wear a respirator are afforded certain medical removal protection relative to retention of earnings, seniority, rights and benefits. The Agency believes that these provisions will encourage all employees, including those experiencing difficulty with respirator use, to participate in the Medical Surveillance Program and will minimize an employee's fear of losing his or her job due to the possible inability to wear a respirator.

Paragraph (f)(5)(i) requires the employer to perform either quantitative or qualitative face fit tests in accordance with the procedures outlined in Appendix B of this section.

Quantitative fit testing is an assessment of the adequacy of respirator fit by numerically measuring the amount of leakage into the facepiece. One method of accomplishing this assessment utilizes a procedure whereby the level of penetration of a test agent of a known concentration is measured inside the facepiece of the respirator. In this quantitative fit test procedure, the respirator is worn in a stable test atmosphere containing a suitable challenge agent. The adequacy of fit is determined by measuring the actual levels of the challenge agent, both outside and inside the facepiece of the respirator. This provides a quantitative assessment of the fit (the fit factor). Fit testing allows the employer to continue testing different facepieces until a properly fitting respirator is identified and selected for the employee. Quantitative fit testing requires the use of moderately sophisticated testing equipment and is more expensive to perform than qualitative fit testing, which may reduce its availability in some work sites. Also, testing services may not be available in all parts of the country to provide quantitative fit testing services for small businesses.

Qualitative fit testing does not provide a numerical measure of the quality of the fit but simply determines whether a respirator fits or not. The outcome of the test is simply a pass or fail result. Qualitative fit testing involves the detection of a gas, vapor, or aerosol challenge agent through subjective means such as odor, taste, or nasal irritation. If the challenge agent's presence is detected, the respirator fit is considered to be inadequate. Qualitative fit testing is more subjective than quantitative testing because it depends on the individual's ability to detect the test agent.

OSHA believes that while quantitative fit testing has some advantages, qualitative fit testing conducted in accordance with the protocols described in Appendix B of this section can generally accomplish the intent of the standard, which is to assure that each employee is assigned and wears a respirator that provides a proper fit.

Paragraph (f)(5)(ii) states that the employer shall assure that each employee who must wear tight-fitting respirator passes a fit test: (A) at the time of initial fitting; (B) whenever changes occur in the employee's facial characteristics that affect the fit of the respirator; (C) whenever a different size or make of respirator is used; and (D) at least annually thereafter unless the annual determination required under paragraph (g)(3)(ii)(A), Medical Surveillance, indicates that the annual

fit test of the employee is not necessary. This frequency of fit testing is necessary to assure that factors that may affect the proper fit of a respirator are detected and necessary adjustments are performed to assure the integrity of the faceseal. For example, the fit of respirators is not standardized among manufacturers. Fit testing would be required, therefore, whenever a different size or make of respirator is used. In addition, a change in an employee's facial structure can compromise a respirator's faceseal. Examples of such changes include loss of weight, cosmetic surgery, facial scarring, and the installation of dentures or the absence of dentures that are normally worn by the individual. Therefore, fit testing is required when any facial changes, such as those mentioned above, occur.

Requiring annual fit testing, unless the annual determination by the physician or other licensed health care professional indicates that the annual fit test is not necessary, assures that factors that could affect respirator fit are detected and the employee's respirator is adjusted or replaced as necessary. It is OSHA's intent in this provision that each employee be evaluated annually for respirator fit. This can be accomplished through either an actual fit test or through a person-to-person evaluation consisting of a questionnaire and personal observation by the evaluator carried out under paragraph (g)(3)(ii)(A), Medical Surveillance, of this section. It should be noted that an annual determination of respirator fit is required, either through fit testing or the person-to-person evaluation. The employer may use the determination of the need for the annual fit test in lieu of an annual fit test if that determination indicates that a fit test is not necessary.

One of the criteria that must be satisfied when selecting respirators is a faceseal leakage of 10% or less. OSHA considers any respirator that passes a qualitative fit test to meet this criteria. However, quantitative fit testing necessitates that a particular numerical value be achieved. Therefore, paragraph (f)(5)(iii) requires that when quantitative fit testing is performed, the employer shall not permit an employee to wear a tight-fitting respirator unless a minimum fit factor of one hundred (100) is obtained in the test chamber. This value corresponds to a faceseal leakage of 10% or less.

In order to assure that continuing protection is achieved by reusable and powered air purifying respiratory protective devices, it is necessary to establish and implement proper maintenance and care procedures. A lax attitude toward this part of the respiratory protection program will negate successful selection and fit because the devices will not deliver the assumed protection unless they are kept in proper working order. A basic program for assuring proper respirator function would contain procedures for cleaning, inspection, repair, and replacement of respirators used in the workplace.

Paragraph (f)(6)(i) requires that the employer clean and disinfect the respirators using the manufacturer's recommended procedures at the following intervals: (A) as necessary for respirators issued for the exclusive use of an employee; and (B) after each use for respirators issued to more than one employee. Respirators that are not cleaned and disinfected can cause skin irritation and dermatitis. When more than one employee uses the same respirator, cleaning and disinfecting after each use provides the additional benefit of minimizing the respirator's role as a vehicle for spreading infections (e.g., skin, respiratory) between employees.

In order to assure continued respirator reliability, they must be inspected on a regular basis. Therefore, paragraph (f)(6)(ii) requires that respirators be inspected before each use and during cleaning after each use. As stipulated in paragraph (f)(6)(iii), such inspections must include: (A) a check of respirator function, tightness of connections and condition of the facepiece, head straps, valves, connecting tube, and cartridges, canisters, or filters; and (B) a check of the rubber or elastomer parts for pliability and signs of deterioration. In this way, the employer can assure that the respirator is functioning as intended, is able to be adjusted by the user, will not allow leakage through cracks or breaks in the respirator, and is pliable enough to achieve a proper faceseal.

The standard also contains provisions regarding those respirators that are found to be deficient upon inspection. Paragraph (f)(6)(iv) states that respirators that fail to pass inspection must be removed from service and repaired or adjusted in accordance with the following: (A) repairs or adjustments to respirators are only to be made with NIOSH-approved parts designed for the respirator by the respirator manufacturer and by persons appropriately trained to perform such operations; (B) only repairs of the type and extent covered by the manufacturer's recommendations may be performed; and (C) reducing or admission valves or regulators shall be returned to the manufacturer or given to an appropriately trained technician for adjustment or repair. It is self-evident that repairs to respirators should only be performed by trained individuals, using parts designed for the specific respirator under repair (not all respirator designs are identical), and that the individual should not attempt repairs that he or she is not qualified to undertake or which are not recommended by the manufacturer.

Another important aspect of assuring appropriate respirator function is proper storage. Therefore, paragraph (f)(6)(v) stipulates that the employer assure that respirators are stored in a manner that protects them from contamination, damage, dust, sunlight, extreme temperatures, excessive moisture, damaging chemicals and that prevents deformation of the facepiece or exhalation valve. Proper storage, of both new respirators and those already in service, assists in maintaining appropriate respirator function by minimizing conditions that may cause deterioration of the respirator or filter, interfere with filter efficiency, change faceseal geometry, and prevent sealing of valves against inhalation of contaminated air.

As discussed previously, OSHA accepts those respirators certified by MSHA and NIOSH. Therefore, paragraph (f)(7)(i) requires that filters, cartridges, and canisters used in the workplace are properly labeled and color-coded with the NIOSH approval label as required by 30 CFR part 11 or 42 CFR part 84, whichever is applicable, before they are placed into service. The employer must assure that the existing NIOSH approval label on a filter, cartridge, or canister is not intentionally removed, obscured, or defaced while it is in service in the workplace, as required by paragraph (f)(7)(ii) of this section.

Paragraph (f)(8) requires the employer to review the overall respiratory protection program at least annually, and conduct inspections of the workplace as necessary to assure that the provisions of the program are being properly implemented for all affected employees. The reason an employer must conduct an annual review and inspections as necessary is because respirators are utilized as supplemental and, in some instances, sole protection to prevent transmission of infectious TB. Therefore, it is of primary importance to assure proper implementation of the program. The review of the program must include an assessment of each element required under paragraph (f)(2) of this section. Once the respiratory protection program is implemented, the employer retains responsibility for detecting and

addressing problems that arise. While the written respiratory protection program is required to be reviewed and updated under paragraph (f)(2)(iii) of the standard, the overall review requires that the employer evaluate actual implementation in the workplace. Consequently, this provision stipulates inspections of the workplace and an assessment of each element required under paragraph (f)(2) of this section to assure proper implementation of the program.

OSHA believes that the proposed provisions regarding respirators are both appropriate and justified. OSHA seeks comments and data on all aspects of the proposed respirator requirements.

Paragraph (g) Medical Surveillance

(1) General

The purpose of this section is early detection and prevention of disease through employee medical histories and physical examinations, TB skin testing, medical management and follow-up of exposure incidents and skin test conversions, and medical removal of employees with suspected or confirmed infectious TB. These requirements are designed to ensure early detection of TB infections and disease by providing appropriate medical examinations to enable identification of infection or disease and to minimize the spread of TB to other employees in the workplace. Additionally, there are requirements in this section to assure that employees required to wear respiratory protection are evaluated to determine their ability to wear a respirator and advised about the need for annual fit testing. The needs of employees who have health conditions that might require special attention are also addressed (e.g., anergy testing, more frequent screening, or further medical examinations to diagnose TB).

Paragraph (g)(1) calls for medical surveillance to be provided for each employee who has occupational exposure, as defined in this standard. Occupational exposure may result in TB infection and the subsequent development of TB disease. Paragraphs (c)(1)(i, ii), (exposure determination) require the employer to identify employees with occupational exposure in the facility. These employees must be offered medical surveillance.

OSHA believes that early detection and management of exposed employees helps prevent severe illness and death. According to CDC's 1994 edition of the Core Curriculum on Tuberculosis (Ex. 7–93), approximately ten percent of the persons infected will develop active TB disease at some point in their lives (Exs. 4B, 7–50, 7–93). Five per cent of those infected develop disease within the first two years following infection and another five percent develop disease later in their lives. Immunosuppressed persons are at a considerably greater risk of developing active disease following a TB infection. For example, individuals infected with HIV and TB have been estimated to have a 8–10% risk per year of developing active disease (Ex. 7–50). However, according to the American Thoracic Society:

> Clinical trials have shown that daily isoniazid preventive therapy for 12 months will reduce the risk of developing tuberculosis in infected persons by about 70 percent and in over 90 percent of patients who are compliant in taking the medications. (Ex. 5–80)

Most infected people have a positive reaction to the TB skin test within 2–10 weeks after exposure. Consequently, early detection of newly infected workers is critical as it permits early initiation of appropriate therapy and results in a decrease in morbidity and mortality.

Paragraph (g)(1)(ii) requires that information about the signs and symptoms of pulmonary tuberculosis disease, a medical history, a physical examination, TB skin testing, medical management and follow-up, and if indicated, other related tests and procedures and medical removal protection if the employee develops infectious TB, be provided to each employee in work settings described in paragraph *(a) Scope* who sustains an ''exposure incident.'' This provision is applicable when the employee has not been categorized as having occupational exposure in the employer's Exposure Control Plan. OSHA recognizes that there may be times when employees who are not ''reasonably anticipated'' to have occupational exposure to TB may be exposed, (e.g., if engineering controls break down or an individual with infectious tuberculosis is unidentified during intake procedures). Employees exposed under such circumstances incur the risk of TB infection and subsequent disease (Ex. 7–93) as a result of their work duties. OSHA includes this provision so that these employees are provided protection.

Paragraph (g)(1)(iii)(A) requires the employer to provide all medical surveillance at no cost to the employee. This is consistent with OSHA policy. Providing services at no cost to the employee is an important factor in successful workplace health and safety programs because it encourages employee participation in medical surveillance programs.

Paragraph (g)(1)(iii)(B) requires that all medical surveillance be provided at a reasonable time and place for the employee. Convenience of these procedures increases the likelihood of employee participation in the program. This helps assure that employees receive the full benefits provided by the standard. OSHA recognizes the need for this provision and has included it in other standards (e.g., Ethylene Oxide, 29 CFR 1910.1047; Asbestos, 29 CFR 1910.1001; and Bloodborne Pathogens 29 CFR 1910.1030).

Paragraph (g)(1)(iii)(C) states that all medical surveillance is required to be performed by or under the supervision of a physician or other licensed health care professional, as appropriate. OSHA has included in paragraph *(j) Definitions,* a description of the licensed health care professional. Such an individual is a physician or other health care professional who holds a license enabling her or him to independently provide or be delegated the responsibilities to provide some or all of the health care services required by this paragraph. In several states, nurse practitioners may be licensed to independently perform or supervise the evaluations and procedures required by this paragraph. In such cases, the requirements of this standard can be accomplished by those practitioners. In addition, where registered nurses are licensed to perform or supervise some of the requirements of this standard, those requirements can be accomplished by those professionals.

Paragraph (g)(1)(iii)(D) requires that medical surveillance procedures be provided according to recommendations of the CDC, current at the time these procedures are performed, except as specified by this paragraph (g). In other words, employers must comply with paragraph (g), and with the most current CDC recommendations in providing medical surveillance. OSHA has set forth what an employer must do to prevent or minimize occupational exposure in the employer's workplace. However, CDC, an agency of the U.S. Public Health Service (USPHS), follows the epidemiology of *M. tuberculosis* and periodically revises and updates its guidelines and recommendations to reflect changes in the diagnosis and treatment of TB. OSHA believes that in addition to meeting the requirements of paragraph (g), it is appropriate to follow CDC recommendations, which address screening, medical evaluations, TB skin test procedures and follow-up (e.g., the administration and interpretation of skin tests).

OSHA recognizes the dynamic nature of medical knowledge relating to

tuberculosis and notes that CDC recommendations current at the time of the standard's publication may differ from recommendations at some future time when an employee evaluation takes place. Knowledge about tuberculosis is expanding. For example, the medical response to HIV/AIDS as related to tuberculosis continues to evolve. These are the reasons why OSHA has not simply required the employer to comply with a particular CDC guideline. OSHA believes that incorporating the CDC recommendations into the standard by reference enhances the quality of medical surveillance. This assures that employees are provided the most current and effective evaluation and treatment. Furthermore, the CDC recommendations provide consistency with regularly updated medical science and health care practice. A similar provision was included in the Bloodborne Pathogens standard 29 CFR 1910.1030 and met with widespread acceptance from the regulated community. The CDC recommendations cover the specific details of the medical protocols.

Paragraph (g)(1)(iv) requires that all laboratory tests be performed by an accredited laboratory. Accreditation by a national accrediting body or its state equivalent means that the laboratory has participated in a recognized quality assurance program. (For an explanation of ''accredited laboratory'' see paragraph *(j) Definitions* below). This accreditation process is required to assure a measure of quality control so that employees receive accurate information concerning their laboratory tests. The accreditation requirement assures long-term stability and consistency among laboratory test procedures and interpretations of results. OSHA recognizes the need for this requirement and has included it in other standards (e.g., Benzene, 29 CFR 1910.1028; Bloodborne Pathogens, 29 CFR 1910.1030).

(2) Explanation of Terms

This paragraph explains the terms used in paragraph *(g) Medical Surveillance.* Paragraphs (g)(2)(i) to (g)(2)(vii) include explanations of the ''medical history'', the ''physical examination (with emphasis on the pulmonary system, signs and symptoms of infectious tuberculosis, and factors affecting immunocompetence)'', ''TB skin testing'', the ''face-to-face determination of ability to wear a respirator and need to be re-fit tested'', ''medical management and follow-up'', ''other related procedures or tests determined to be necessary'', and ''Medical Removal Protection''. The applications section, paragraph (g)(3), describes what must be provided and at what time.

Paragraph (g)(2)(i) describes a medical history, during which the examiner questions the employee in order to gather information on the employee's pulmonary system, TB exposure, vaccination, testing and disease status and factors affecting immunocompetence. A medical history questionnaire may be used as a starting point for this discussion. OSHA believes that a medical history is essential for interpreting the TB skin test results, which are also required by this paragraph (g). The CDC Core Curriculum states:

> TB skin testing is a useful tool, but is not perfect. Several factors can affect the skin test reaction: for example, infection with mycobacteria other than *M. tuberculosis* and vaccination with BCG. These factors can lead to false-positive reactions * * * Other factors, such as anergy, can lead to false-negative reactions. (Ex. 7–93).

Therefore, the medical history is used to assist in interpreting the TB skin test results. The medical history also provides information regarding the employee's potential for increased risk if exposed to tuberculosis. Based on this information, discussions between the employee and the examiner regarding the employee's increased risk can assist the employee in decision-making.

Paragraph (g)(2)(ii) describes the physical examination. The physical examination is to emphasize the pulmonary system, signs and symptoms of active TB disease, and factors affecting immunocompetence. Such an examination assists the examiner in detecting evidence of active disease (e.g., rales), differentiating TB disease from other causes of cough or other signs/symptoms associated with TB disease, and ascertaining whether signs are present that are compatible with an immunocompromising health condition. The physical examination is also required when an employee has signs or symptoms of TB or after a TB skin test conversion and at other times, if indicated.

That the pulmonary system is emphasized in both the medical history and physical examination assures that the employee is evaluated with specific attention to the most common site of infectious TB. Although extrapulmonary tuberculosis can occur (e.g., in bone, meninges of the brain, and draining abscesses), it is not usually a source of infection for others. The language ''with emphasis on the pulmonary system'' is used to indicate that while the history and physical examinations evaluate the health of the patient as a whole, particular emphasis should be placed on the pulmonary system.

Paragraph (g)(2)(iii) explains the required TB skin testing. TB skin testing is the cornerstone for early detection of TB transmission among exposed workers. The American Thoracic Society notes that:

> Although currently available TB skin tests are substantially less than 100% sensitive and specific for detection of infection with *M. tuberculosis*, no better diagnostic methods have yet been devised. (Ex. 5–4)

The TB skin test is an important tool that is useful in identifying employees who may be eligible for appropriate, early treatment; initiating contact investigations; and evaluating the effectiveness of the facility's control program. The requirement for TB skin testing is supported by AHA (Exs. 7–61, 7–29), APIC (Ex. 7–30), AIHA (Ex. 7–170) and the CDC 1994 Core Curriculum which states, ''TB screening should be done in groups for which rates of TB are substantially higher than the general population.'' [Ex. 7–93]. In this document, CDC specifically mentions screening for health care workers, staff of long term care facilities, correctional facilities, hospices, drug treatment centers, and nursing homes.

Paragraph (g)(2)(iii) describes the requirement for TB skin testing. TB skin testing, which only applies to employees whose TB skin test status is not known to be positive, includes anergy testing if indicated, and consists of an initial 2-step protocol for each employee who has not been previously skin tested and/or for whom a negative test in the past 12 months cannot be documented. If the employer has documentation that the employee has had a negative TB skin test within the past 12 months, that test may be used to fulfill the skin testing portion of the initial medical surveillance requirements. For example, if an employer has a new or existing employee for whom: (1) a TB skin test has not previously been performed, or (2) a negative skin test result within the past 12 months that cannot be documented, the employer is required to provide an initial two-step skin test for the employee. Conversely, if the employer can document a negative skin test result from a test performed on the employee within the past 12 months, that test can be used to fulfill the initial skin testing requirement of this section. Subsequent periodic retesting of the employee is to be performed in accordance with paragraph (g)(3), as discussed below.

It is important for the employer to determine the current TB skin test status

of employees prior to their initial assignment to a job with occupational exposure. This ''baseline'' status can then be used to evaluate changes in the employees' TB skin test.

In their 1992 guidelines, the American Thoracic Society recommended the following:

> Individuals at high risk for TB should have a TB skin test at least once to assess their need for preventive therapy and to alert the health care providers of those with positive skin tests of this medical problem. In institutional settings, baseline information on the TB skin test status of staff and residents is a means of identifying candidates for preventive therapy as well as determining whether transmission of TB is occurring in the facility. For this reason, TB skin testing upon employment or upon entry should be mandatory for staff and residents * * * (Ex. 5–80)

Previous BCG vaccination is not a contraindication for skin testing. In its 1994 guidelines, the CDC states:

> During the pre-employment physical or when applying for hospital privileges, HCWs who have the potential for exposure to *M. tuberculosis* [sic], including those with a history of BCG vaccination, should have baseline PPD skin testing performed * * *
>
> BCG vaccination may produce a PPD reaction that cannot be distinguished reliably from a reaction caused by infection with *M. tuberculosis.* For a person who was vaccinated with BCG, the probability that a PPD test reaction results from infection with *M. tuberculosis* increases (a) as the size of the reaction increases, (b) when the person is a contact of a person with TB, (c) when the person's country of origin has a high prevalence of TB, and (d) as the length of time between vaccination and PPD testing increases. For example, a PPD test reaction of ≥10 mm probably can be attributed to *M. tuberculosis* in an adult who was vaccinated with BCG as a child and who is from a country with a high prevalence of TB. (Ex. 4B)

CDC does not state that BCG vaccination negates the need for baseline and periodic skin testing but does state that skin tests on vaccinated individuals need to be interpreted carefully. OSHA's proposed rule is consistent with the CDC Guidelines on this point. PPD testing is thus not contraindicated for BCG vaccinated employees; however, such prior vaccination does mean that other factors, such as the age of the employee and the extent of induration, must be considered in interpreting the results.

The purpose of performing a *two-step test* is to correctly identify the baseline TB skin test status of those employees who are infected with TB but whose sensitivity to the tuberculin testing material may have waned over the years. This procedure enhances the proper interpretation of subsequent positive TB skin test results and is based upon current CDC and American Thoracic Society recommendations (Exs. 5–80, 6–15, 7–52, 7–93, 7–169).

Two-step testing requires an employee to be tested initially and, if the test results are negative, to be tested again within 1–3 weeks. This second test stimulates or ''boosts'' the body's response to the testing material and results in a more valid reaction. For example, an employee who has not been recently tested but who is infected with TB from an earlier exposure may fail to respond to this current test because his or her immune response has waned over time. However, a second test of this employee will produce a positive TB skin test that more accurately reflects his or her true TB skin test status. Thus, the initial use of a two-step testing procedure ensures that the baseline TB skin test is an accurate reflection of the employee's TB status and will reduce the likelihood of misinterpreting a ''boosted'' reaction on subsequent tests as a conversion. Two-step testing is also appropriate for individuals who have been BCG vaccinated, since these individuals can exhibit a boosted reaction. Therefore, two-step testing of BCG vaccinated individuals can be used to determine their baseline status, although the skin test results must be interpreted in light of their previous BCG vaccination.

The two-step testing procedure does not identify those persons who are truly anergic and, therefore, are not capable of mounting a typical immune response to the test material. Evaluation of adequate immune response, when determined to be necessary by the physician or other licensed health care professional, as appropriate, is determined through anergy testing, and this is provided for in the explanation of TB skin testing in paragraph (g)(2)(iii).

The CDC recommendations are the guiding documents for TB skin test protocols. By referring the employer to these recommendations in Paragraph (g)(1)(iii)(D), OSHA allows for future changes in protocols and procedures that result from continuing research. Consistent with the CDC guidelines (Exs. 3–33, 3–35, 3–32, 6–15), the American Thoracic Society recommends:

> The Mantoux test with 5 Tuberculin Units (TU) of PPD may be used as a diagnostic aid to detect tuberculous infection and to determine the prevalence of infection in groups of people. (Ex. 5–4)

Proper administration of a TB skin test results in a reaction described as a classic example of a delayed (cellular) hypersensitivity reaction. This reaction indicates infection with mycobacterium, most commonly *M. tuberculosis.* The reaction characteristically begins in 5–6 hours, is maximal at 48–72 hours, and subsides over a period of days (Ex. 5–4).

Proper administration and interpretation of the test is critical and can be complex. In 1990, the American Thoracic Society revised the criteria for interpreting the TB skin test (Ex. 5–4). Information such as the health status of the tested employee, history of BCG vaccination, recent close contact with persons with active TB, chest x-ray results, and other factors must be considered when interpreting the TB skin test results. CDC has established criteria for a TB skin test *conversion*; that is, when an employee's TB skin test results change from negative to positive, indicating a recent TB infection (Ex. 4–B).

Because of the complexity in properly administering and interpreting TB skin tests, it is essential that only trained individuals perform this function. For this reason, TB skin testing is to be administered and interpreted by or under the supervision of a physician or other licensed health care professional as appropriate and according to CDC recommendations. This language allows employers to chose from a variety of health care professionals who can administer and interpret TB skin tests. OSHA is aware that in some worksites, employees have been allowed to read and interpret their own skin test results. A surveillance system that allows self-reading and interpretation of TB skin tests can be problematic. With regard to interpretation of TB skin test results, the American Thoracic Society states:

> Intelligent interpretation of skin test results requires a knowledge of the antigen used (tuberculin), the immunologic basis for the reaction to the antigen, the technique(s) of administering and reading the test, and the results of epidemiologic and clinical experience with the test. (Ex. 5–4)

In its 1994 *Core Curriculum on Tuberculosis* (Ex. 7–93), CDC describes the complexities of interpreting the induration resulting from TB skin testing. A number of factors can affect the size of a TB skin test induration relative to whether or not the test should be interpreted as being positive. For example, induration of 5 mm or more is classified as positive for persons with known or suspected HIV infection, while an induration must be 10 mm to be classified as positive in persons who are foreign-born in high prevalence countries. An induration of 15 mm or more is classified as positive in certain other situations. In addition, TB skin

testing can result in both false positive and false negative results.

Clearly, interpreting TB skin test results requires professional expertise and must be performed by or under the supervision of a physician or other licensed health care professional, as appropriate, by an individual with training and experience in performing the test and interpreting the result. Proper use of the TB skin test as a medical surveillance tool will require two visits to the health care professional: one to receive the test and one to read/interpret the test results. However, considering the critical importance of this element, OSHA believes that allowing employees to read and interpret their own tests or allowing their peers to do so (unless they meet the criteria discussed above) compromises the quality and accuracy of the testing procedure.

Paragraph (g)(2)(iv) describes the determination of each employee's ability to wear a respirator and of his or her need for re-fit testing for employees required to wear a respirator. This face-to-face determination includes a verbal exchange between the employee and the examiner regarding the employee's health factors such as illness or injuries, that may impact his or her ability to wear a respirator (e.g. vascular or heart disease, asthma, claustrophobia, facial structure defects, certain skin conditions, etc.) (Ex.7–64). Based on this history and the observation of the employee, the need for further testing or physical examinations for the ability to wear a respirator can be determined. In addition, assessment of the need for re-fit testing is to be performed, which assures that the examiner consider whether re-fit testing is needed. OSHA has included a note stating that the determination of the need for re-fit testing may only be performed after the required initial fit test of the employee and cannot be used in lieu of any other required fit tests, as, for example, when a different size or make of respirator is used.

Paragraph (g)(2)(v) explains that medical management and follow-up include diagnosis, and, where appropriate, prophylaxis and treatment related to TB infection and disease. The employer must provide medical management and follow-up for occupationally exposed employees with skin test conversions [paragraph (g)(3)(i)(D)], or those who undergo an exposure incident whether or not they are categorized as occupationally exposed [paragraphs (g)(1)(ii) and (g)(3)(i)(C)]. In addition, any time an occupationally exposed employee develops signs and symptoms of infectious tuberculosis, medical management and follow-up are required [paragraph (g)(3)(i)(B)]. John E. McGowan addressed follow-up in the 1995 article entitled ''Nosocomial Tuberculosis: New Progress in Control and Prevention,'' published in Clinical Infectious Diseases. He states,

> If the PPD skin testing program for health care workers is to be useful, several steps are crucial. * * * The institution also must make sure that the occupational health service undertakes careful follow-up of workers found to have positive TB skin tests or tuberculosis disease. This follow-up should include counseling, careful monitoring of therapy (when prescribed) until its completion and evaluation of fitness to return to work. (Ex. 7–248).

Paragraph (g)(2)(vi) explains that other related tests and procedures are any TB-related tests and procedures determined to be necessary by the physician or other licensed health care professional, as appropriate. These procedures or tests could include chest radiographs, sputum smears, or other testing determined to be necessary to make an assessment, a diagnosis, or medically manage the employee. An example of a program that integrates testing and examinations was given at the 1994 meeting of the Society for Occupational and Environmental Health, by Carol Murdzak who presented the University of Manitoba's Medical Surveillance program. Her presentation, entitled ''Conducting a Medical Surveillance Program to Prevent and Control Transmission of TB in a Health Care Institution'' demonstrates the use of skin testing and general review of health status for employee surveillance. Results of TB skin testing and the review of health status determine the need for chest x-ray and further medical evaluation in this program (Ex.7–169).

(3) Application

Medical examinations in the form of medical histories, physical examinations, TB skin testing and other related tests and procedures are necessary in order to promptly identify and treat employees with infectious tuberculosis.

Paragraph (g)(3), Application, specifies what an employer must provide. In each situation set forth in paragraph (g)(3), the employer must provide medical examinations, tests and procedures as specified. Some of the provisions are offered only ''if indicated,'' which means that the physician or other licensed health care professional, as appropriate, has determined that further tests or procedures are needed. For example, an employee who has no history of illness or being immunocompromised and whose TB skin test is negative at the time of initial assignment is not required to be offered a physical examination unless the examiner determines that a physical examination is indicated. However, if at the time of annual skin test, the employee has a skin test conversion, a physical examination is required.

Paragraph (g)(3)(i)(A) requires that, before the time an employee is initially assigned to a job with occupational exposure (or within 60 days from the effective date of the standard for employees already assigned to jobs with occupational exposure), the employee be provided with a medical history, TB skin testing, and, if indicated, a physical examination and other related tests and procedures.

OSHA requires the initial medical history to assist in assessing the employee's health. This information will provide a baseline health status that can be used to evaluate (1) whether the employee has a pre-existing condition that may be exacerbated by occupational exposure to TB and (2) any future health conditions that may arise that are relevant to occupational exposure to TB.

OSHA does not believe that an initial physical examination for all occupationally exposed employees is necessarily warranted. However, the Agency does believe that a physical examination, if determined to be indicated by the examiner based on the medical history and TB skin test results, is useful and effective.

The note to paragraph (g)(3)(i)(A) specifies that if an employee has had a medical examination within the twelve (12) months preceding the effective date of the standard and the employer has documentation of that examination, only the medical surveillance provisions required by the standard that were not included in the examination need to be provided. The Agency realizes that employees may have received at least some of the elements of the required medical surveillance provisions shortly before the effective date of the standard. In these situations, a full TB examination would not need to be repeated.

In addition, the proposed standard allows the baseline TB skin testing status of an employee to be established by documentation of a TB skin test that was administered within the previous 12 months. For example, if an employee has a written record of a TB skin test within the last 12 months, that information can be used to document the employee's baseline TB skin test status and another TB skin test at the

time of the initial medical examination is not necessary. When utilizing results from a previous medical examination and skin test to fulfill the initial medical surveillance requirements, the employer must use the date(s) of the previous medical exam and skin test to determine the date(s) of the employee's next medical examination and skin test. In no case shall the interval between the previous examination and skin test and the next examination and skin test exceed 12 months. These provisions are designed to avoid unnecessary testing of employees and do not compromise the quality of the medical surveillance.

Information (e.g., medical history) obtained from a medical examination in the past 12 months is unlikely to change within this span of time. However, this may not be the case with regard to previous skin testing results. While OSHA is proposing to accept a skin test performed within the past 12 months as a substitute for performing an initial baseline skin test, an employer utilizing a new employee's negative skin testing result obtained more than 3 months prior to beginning the new job may be uncertain as to the source and time of infection if the employee tests positive at his or her next skin test. More specifically, conversion normally occurs within 3 months of infection. Therefore, an employee would have been negative at his or her last skin test, e.g., 7 months previously, and have been infected just after the skin test and subsequently converted. In such a case, an employer may rely on the previous negative skin test as the baseline does not need to test the new employee until 5 months later (i.e., annual skin test frequency), at which time the employee would test positive and be identified as a converter. In this situation, the new employer would not be able to determine if the employee's conversion had occurred as a result of exposure occurring previous to hire or from exposure in his or her current work setting. Regardless of the source of the conversions, the employer would be required by the standard to initiate medical management and a follow-up investigation, which might also entail skin testing other employees in the worksite to determine if other conversions had taken place, a step that would not be necessary if the employee had been correctly identified as positive upon entry into the workplace. In view of this, employers may choose to perform an initial baseline skin test on each new employee before the employee enters the work setting.

Once an employee is on the job, paragraph (g)(3)(i)(A) requires employers to periodically retest employees who have negative TB skin tests in order to identify those employees whose skin test status changes, indicating that they have been infected. Because the baseline TB skin test provides only a ''snapshot'' of the TB skin test status of the employee and because exposure and subsequent infection can occur at any time, periodic testing is necessary. The American Thoracic Society recommends:

> * * * follow-up skin-testing should be conducted on at least an annual basis among the staffs of TB clinics, health care facilities caring for patients with HIV infection, mycobacteriology laboratories, shelters for the homeless, nursing homes, substance-abuse treatment centers, dialysis units, and correctional institutions. (Ex. 5–80)

When TB exposure results in infection, early identification allows employees to have options regarding prophylactic treatment, thereby reducing the likelihood that the infection will progress to disease.

OSHA recognizes the importance of periodic testing to monitor the status of employee's skin test results. In their 1994 Guidelines for Preventing the Transmission of Tuberculosis in Health-Care Facilities, the CDC recommends that the frequency of PPD skin testing of employees be based upon the individual facility's risk assessment in conjunction with the criteria put forth by the CDC (Ex. 4B). For situations that meet certain CDC criteria, CDC recommends that employees receive a repeat TB skin test every 3 months, six months or annually, depending upon the risk assessment.

OSHA's proposed standard does not require a risk assessment of the type described by CDC and would extend coverage to worksites other than ''health-care facilities'' as described in the CDC document (Ex. 4B). Consequently, OSHA is proposing that repeat TB skin test be performed every 6 months or annually, depending upon the exposure determination. This testing frequency is expected to be both practical and effective in early identification of skin test conversions in the various worksites described in the Scope. The requirements for more frequent TB skin tests (e.g., 3 months after an exposure incident, or if deemed necessary by a licensed health care professional) ensures that employees' health is not compromised.

An exemption to this annual testing is permitted for an employer who can demonstrate that his or her facility or work setting: (1) Does not admit or provide medical services to individuals with suspected or confirmed infectious TB, (2) has had no cases of confirmed infectious TB in the past 12 months, and (3) is located in a county that, in the past two years, has had 0 cases of confirmed infectious TB reported in one year and fewer than 6 cases of confirmed infectious TB reported in the other year. In these settings only a baseline TB skin test is required. This is discussed earlier under paragraph *b, application.*

Paragraph (g)(3)(i)(B) requires that, when an employee has signs or symptoms of TB, either observed or self-reported, the employee be provided a medical history, physical examination, TB skin testing, medical management and follow-up, and other related tests and procedures determined to be necessary. CDC states that the presence of signs or symptoms of tuberculosis in the employee requires prompt medical evaluation (Ex. 7–52, 7–93), and such evaluation provides an opportunity for initiating drug therapy. Furthermore, identifying those with infectious pulmonary TB disease enables the employer to remove them from the workplace, preventing exposure of other employees.

Paragraph (g)(3)(i)(C) requires that when an employee incurs an exposure incident, a medical history, TB skin testing, medical management and follow-up, and, if indicated, a physical examination and other related tests and procedures be provided. Evaluation and follow-up after each exposure incident help detect any resultant infections, as well as prevent infection in other employees, benefitting the health of all employees.

Following exposure, infected workers will usually develop a positive response to a TB skin test (Exs. 7–50, 7–93, 5–4). In certain cases, workers may also display signs or symptoms compatible with tuberculosis disease such as complaints of persistent cough (over 3 weeks in duration), bloody sputum, night sweats, weight loss, loss of appetite or fever. Use of the TB skin test has been recognized as a tool in the early identification of infection and for disease surveillance and follow-up. In paragraph (g)(3)(i)(C), the proposed standard also requires employers to provide testing for employees as soon as feasible after an exposure incident, unless a negative TB skin test has been documented within the preceding 3 months. If this baseline skin test is negative, another TB skin test shall be repeated 3 months after the exposure incident.

In order to accurately determine if an exposure incident has resulted in infection, the employer must first know the baseline skin test status of the affected employee(s) at the time of the exposure incident. Typically, skin test conversion can be documented approximately 2–10 weeks following

infection (Ex. 7–52). Consequently, it can be reasonably assumed that a negative TB skin test within the three months prior to the incident is sufficiently indicative of the employee's status at the time of the exposure incident.

For those employees who do not have a documented negative skin test within the past three months, the employer must determine their TB skin test status as soon as feasible after the exposure incident. The requirement of ''as soon as feasible'' in the provision puts the employer under the obligation of performing the TB skin test quickly, i.e., before infection resulting from the exposure would be manifested as a conversion. This assures that a true indication of the employee's skin test status at the time of the incident is obtained.

The purpose of the initial TB skin test following an exposure incident is to establish the TB skin test status of the employee(s) at the time of the incident. From this baseline, changes in TB skin test status can be identified. This initial test would not detect infection resulting from the exposure, since there would not have been sufficient time for conversion to occur. Hence, the employer is required to provide a repeat TB skin test three months after the exposure incident to determine if infection has occurred. This requirement reflects current CDC recommendations (Ex. 4B).

Paragraph (g)(3)(i)(D) requires that when an employee has a TB skin test conversion, the employee receive a medical history, a physical examination, medical management and follow-up, and other tests and procedures determined to be necessary. This provision assures that employees with skin test conversions receive appropriate evaluation for preventive therapy and for infectious tuberculosis. OSHA included the provision for early identification of disease since, as the CDC has stated in their guidelines, infectious tuberculosis disease can be prevented by the early treatment of tuberculosis infection.

In paragraph (g)(3)(i)(E), the proposed standard requires employers to provide TB skin testing within 30 days prior to termination of employment. The rationale for this requirement is two-fold. First, this requirement permits employees whose employment is terminated after an unrecognized exposure incident, but before their next regularly scheduled TB skin test, to determine their current (exit) TB skin test status. OSHA recognizes that in some instances employees may be in the process of converting from negative to positive TB skin test results at the time of the exit testing and that some of these cases will be missed. Also missed will be employees who decline testing or who vacate their position immediately or without notice. While such situations are possible, the Agency believes that these occurrences would be rare. Secondly, by detecting recent conversions, appropriate steps can be taken by the employer to investigate the cause of the exposure. This helps prevent future exposures in those areas or situations where the exiting employee's infection may have occurred.

Paragraph (g)(3)(i)(F) requires that a medical history, physical examination, TB skin testing, determinations of the employee's ability to wear a respirator, medical management and follow-up or other related tests and procedures be conducted at any other time determined necessary by the physician or other licensed health care professional, as appropriate. This allows the physician or other licensed health care professional, as appropriate, to recognize the individual differences in employees' medical status and response to TB infection and increase the frequency or content of examination as needed. Some workers who have certain health conditions may need more frequent evaluation (Ex. 4B). For example, individuals who have a condition that may interfere with an accurate interpretation of TB skin test results (e.g., the development of test anergy in an employee who is on chemotherapy for cancer treatment), may warrant more frequent evaluations because of the high risk for rapid progression to TB disease if he or she becomes infected. (Ex. 4B)

Paragraph (g)(3)(ii) sets forth provisions regarding employees who wear respirators. Paragraph (g)(3)(ii)(A) requires that a face-to-face determination of the employee's ability to wear the respirator be accomplished before initial assignment to a job with occupational exposure (or within 60 days of the effective date of the standard) and at least annually thereafter. As discussed above under explanation of terms, this is a verbal exchange to assess health factors that could affect the employee's ability to wear a respirator. An initial determination is made before assignment to a job requiring respirator use to assure that the employee's health factors have been properly evaluated prior to incurring exposure to *M. tuberculosis.* This determination must also be made annually to assure that no health conditions have arisen that might limit an employee's ability to wear a respirator.

Such conditions may arise and be noted prior to the annual determination. For example, the employee may experience unusual difficulty while being fitted or while using the respirator. In these situations, it is not appropriate to wait until the annual determination. Therefore, paragraph (g)(3)(ii)(B) requires that a face-to-face determination of the employee's ability to wear a respirator, including relevant components of a medical history and, if indicated, a physical examination and other related tests and procedures, be provided whenever the employee experiences unusual difficulty while being fitted or while using a respirator.

Paragraph (g)(3)(iii) requires employers to provide TB skin tests every 6 months for each employee who enters AFB isolation rooms or areas, performs or is present during the performance of high-hazard procedures, transports or is present during the transport of an individual with suspected or confirmed infectious TB in enclosed vehicles, or works in intake areas where early identification is performed in facilities where 6 or more individuals with confirmed infectious TB have been encountered within the past 12 months. OSHA believes that employees who perform these activities are exposed more intensely and frequently to individuals with suspected or confirmed infectious tuberculosis and should, therefore, be tested more frequently.

(4) Additional Requirements

Paragraph (g)(4) (i) through (iv) contain the additional requirements an employer must meet. Paragraph (g)(4)(i) requires that the physician or other licensed health care professional, as appropriate, verbally notifies the employer and the employee as soon as feasible if an employee is determined to have suspected or confirmed infectious tuberculosis. In this way an infectious employee can be removed from the workplace, thereby minimizing occupational exposure for other workers. Paragraph (g)(7)(i), Written Opinion, allows 15 days before the employer must provide the employee with the written opinion of medical evaluations from the physician or other licensed health care professional, as appropriate. In situations where an employee is determined to be potentially infectious, this time period leads to unnecessary delays in removal from the workplace and disease treatment. Therefore, OSHA requires the verbal notification to expedite treatment

and prevent spread of disease to other employees.

The proposed standard, in paragraph (g)(4)(ii), requires the employer to notify each employee who has had an exposure incident when the employer identifies an individual with confirmed infectious TB who was previously unidentified. For example, if a newly admitted patient undergoes diagnostic and therapeutic evaluation for suspected pulmonary malignancy, and the diagnosis of infectious tuberculosis is not made until several days after hospitalization, all hospital staff who have had exposure must be identified and provided TB skin test and follow-up. OSHA intends to assure that employees are provided with opportunities for early detection of tuberculosis infection. These provisions are consistent with the general purpose of tuberculosis medical surveillance as recommended by the CDC, and they are included to assist all employees in receiving the full benefits provided by the standard.

Determination of the drug susceptibility of the *M. tuberculosis* isolate from the source of an exposure incident resulting in a TB skin test conversion is required by paragraph (g)(4)(iii) unless the employer can establish that such a determination is infeasible. Information regarding drug susceptibility assists the examiner in deciding the most effective treatment therapy for the exposed employee, particularly if the source is a drug resistant strain of *M. tuberculosis.* Drug susceptibility testing of the source isolate is recommended by CDC (Ex. 4B). OSHA includes the provision regarding infeasibility because certain TB skin test conversions may involve unknown exposure sources. This can make identification of the isolate and therefore drug susceptibility testing infeasible or even impossible. It is the responsibility of the employer to establish that this is infeasible, if such is the case. Employers must make a good faith effort to identify *M. tuberculosis* isolates and obtain the drug susceptibility testing.

Paragraph (g)(4)(iv) requires the employer to investigate and document the circumstances surrounding an exposure incident or TB skin test conversion and to determine if changes can be instituted that will prevent similar occurrences in the future.

The provision assures that employers obtain feedback regarding the circumstances of employee exposures and use the information to eliminate or decrease specific circumstances leading to exposure. For example, exposure incident investigation shows that an employee was exposed to tuberculosis as a result of recirculation of air containing infectious droplet nuclei. Further investigation shows inadequate local or general ventilation in the workplace. The employer can now repair the ventilation system and prevent future exposure incidents. Another example of corrective measures may be including a stronger training emphasis on certain procedures where proper work practices might have decreased the likelihood of transmission of tuberculosis. Employers can obtain further guidance regarding investigations for TB skin test conversions and exposure incidents in health care workers by reading the 1994 CDC guidelines.

(5) Medical Removal Protection

Paragraph (g)(5)(i) requires that employees with suspected or confirmed infectious tuberculosis be removed from the workplace until determined to be non-infectious according to current CDC recommendations. Infectious TB is contagious and removal is essential for the protection of other workers. An employee's ''infectiousness'' is determined by the physician or other licensed health care professional, as appropriate, who informs the employer as required in paragraphs (g)(4)(i) and (g)(7) of this section.

Paragraph (g)(5)(ii) states that for employees removed from the workplace under paragraph (g)(5)(i), the employer shall maintain the total normal earnings, seniority, and all other employee rights and benefits, including the right to former job status, as if the employee had not been removed from the job or otherwise been medically limited until the employee is determined to be noninfectious or for a maximum of 18 months, whichever comes first. Paragraph (g)(5)(iii) provides medical removal protection for employees removed from the workplace under paragraph (f)(4)(viii) of Respiratory Protection. The provision requires the employer to transfer the employee to comparable work for which the employee is qualified or can be trained in a short period (up to 6 months), where the use of respiratory protection is not required. OSHA requires that if no such work is available, the employer shall maintain the employee's total normal earnings, seniority, and all other employee rights and benefits until such work becomes available or for 18 months, whichever comes first.

The requirement referring to the employee's right to return to his or her former job is not intended to expand upon or restrict any rights an employee has or would have had, to a specific job classification or position under the terms of a collective bargaining agreement. Where the employer removes an employee from exposure to tuberculosis, the employee is entitled to full medical removal protection benefits as provided for under the standard.

The medical removal requirement is an indispensable part of this standard. The medical removal protection helps assure that affected employees participate in medical surveillance and seek appropriate care. If employees fear losing their jobs as a result of their medical condition they may attempt to hide the illness, thereby infecting many more workers and other people and jeopardizing their own health. The requirement for medical removal assures that an infectious employee will not be terminated, laid off, or transferred to another job (possibly at a lower pay grade) upon returning to work. Consequently, this protection should reduce reluctance on the part of the employee to participate in medical surveillance. The employee's health will be protected and the health of co-workers and others who come into contact with that employee will be protected, also.

OSHA believes that the cost of protecting worker health to the extent feasible is an appropriate cost of doing business since employers are obligated by the OSH Act to provide safe and healthful places of employment. Consequently, the costs of medical removal, like the costs of respirators and engineering controls, are borne by employers rather than individual workers.

If a removed employee files a claim for workers' compensation payments for a tuberculosis-related disability, then the employer must continue to provide medical removal protection benefits pending disposition of the claim. To the extent that an award is made to the employee for earnings lost during the period of removal, the employer's medical removal protection obligation may be reduced by such amount. The employer's obligation to provide medical removal protection benefits to a removed employee may be reduced to the extent that the employee receives compensation for earnings lost during the period of removal either from a publicly or employer-funded compensation program, or receives income from employment with another employer which was made possible by virtue of the employee's removal.

Medical removal should not be viewed as an alternative to primary control (prevention) of workers' exposure to tuberculosis; rather, it should be used as a secondary means of

protection, where other methods of control have failed to protect. The stipulation of an 18 month time period of protection is consistent with other OSHA standards (e.g., Cadmium, 29 CFR 1910.1027; Lead in Construction, 29 CFR 1926.62). The provision of medical removal and the costs associated with the program may indirectly provide employers with economic incentives to comply with other provisions of the standard. It can be expected that the costs of medical removal will decrease as employer compliance with other provisions of the standard increases.

(6) Information Provided to Physician or Other Licensed Health Care Professionals

Paragraph (g)(6)(i) requires the employer to assure that the health care professionals responsible for the medical surveillance receive a copy of this regulation. OSHA believes it is the employer's responsibility to inform the health care professionals responsible for medical surveillance of the requirements of this standard. This will help assure that these individuals are aware of and implement the requirements. This provision is included in other OSHA standards (e.g., Benzene, 29 CFR 1910.1028; Bloodborne Pathogens, 29 CFR 1910.1030).

Paragraph (g)(6)(ii) requires the employer to assure that the physician or other licensed health care professional, as appropriate, evaluating an employee after an exposure incident receives: (A) A description of the exposed employee's duties as they related to the exposure incident; (B) a description of the circumstances under which the exposure incident occurred; (C) the employee's diagnostic test results, including drug susceptibility pattern, or other information relating to the source of exposure that could assist in the medical management of the employee; and (D) all of the employee's medical records relevant to the medical evaluation of the employee, including TB skin test results. Since the individual responsible for medical surveillance may not necessarily be the person evaluating an employee after an exposure incident, it is necessary to also provide a copy of this standard to the evaluating physician or other appropriate licensed health care professional, as required by paragraph (g)(6)(i). In this way, the evaluator will also be informed of and implement the standard's requirements. All of the above information is essential to follow-up evaluation, and helps assure that an accurate determination can be made regarding appropriate medical treatment of the exposed employee. This provision is consistent with other OSHA standards (e.g., Bloodborne Pathogens, 29 CFR 1910.1030, Benzene, 29 CFR 1910.1028).

(7) Written Opinion

Paragraph (g)(7)(i) states that the employer shall obtain and provide the employee with a copy of the written opinion of the physician or other licensed health care professional, as appropriate, within 15 days of the completion of all medical evaluations required by this section. The purpose of requiring the employer to obtain a written opinion is to assure that the employer is provided with documentation that the medical evaluation of the employee (1) has taken place and that the employee has been informed of the results; (2) has included an evaluation of the employee's need for medical removal or work restriction; (3) describes the employee's TB skin test status so that the employer can assess action needed to prevent further exposure; and (4) informs the employer of the employee's infectivity status so that the employer can take action to prevent the employee from becoming a source of infection for other employees.

The employer has a right to know the information contained in the written opinion and may retain the original written opinion, but must provide a copy to the employee. The 15 day provision assures that the employee is informed in a timely manner regarding information received by the employer and is consistent with other OSHA standards (e.g., Formaldehyde, 29 CFR 1910.1048; Benzene, 29 CFR 1910.1028; Bloodborne Pathogens, 29 CFR 1910.1030).

In addition, the written opinion is required to assure the employer that the employee has been provided with information about any medical conditions resulting from exposure to tuberculosis which require further evaluation or treatment.

OSHA believes it is important that employers know if their employees have had evaluations for tuberculosis infection or exposure incidents, and that physicians or other appropriate licensed health care professionals, acting as agents for the employer, have provided the employer with written documentation that these evaluations occurred. However, paragraph (g)(7)(ii) limits the information the employer is provided in order to protect the privacy of the employee. The requirement for a written opinion after a medical evaluation has been included in other OSHA standards (e.g., Occupational Exposures to Hazardous Chemicals in Laboratories, 29 CFR 1910.1450; Formaldehyde, 29 CFR 1910.1048; Bloodborne Pathogens, 29 CFR 1910.1030).

Paragraph (g)(7)(ii)(E) requires the written opinion to state any recommendations for medical removal or work restrictions and the employee's ability to wear a respirator. This recommendation must be in accordance with paragraphs (g)(5)(i) and (f)(5)(viii) of this section. Including this information in the written opinion assures that the employer is provided with written documentation of the need for removal of an employee with infectious tuberculosis from the workplace. The provision also assures that the employer is aware of any work restrictions on the employee and the employee's ability or inability to wear a respirator. This information enables the employer to take appropriate steps in managing the employee's duties upon return to the workplace. OSHA recognizes the need for this provision and has included it in other standards (e.g., Lead in Construction, 29 CFR 1926.62).

Paragraph (g)(7)(iii) states that all other findings or diagnoses shall remain confidential and shall not be included in the written report. OSHA believes that all health care professionals have an obligation to view medical information gathered or learned during tuberculosis medical surveillance or post-exposure evaluation as confidential medical information. As stated previously, the maintenance of confidentiality encourages participation in medical surveillance by allaying employee concern that medical conditions unrelated to tuberculosis exposure will be communicated to the employer. OSHA also recognizes that successful medical surveillance and medical management and follow-up programs must guarantee this confidentiality, the specific requirements on confidentiality can be found in applicable state and federal laws and regulations that cover medical privacy and confidentiality. Finally, OSHA recognizes the need for this provision and has included it in other standards (e.g., Bloodborne Pathogens, 29 CFR 1910.1030).

Paragraph (h) Communication of Hazards and Training

Paragraph (h), Communication of Hazards and Training, addresses the issues of transmitting information to employees about the hazards of tuberculosis through the use of labels, signs, and information and training. These provisions apply to all operations that come under the coverage of

paragraph (*a*), *Scope*, of this section. Although OSHA has an existing standard, Hazard Communication (29 CFR 1910.1200), which requires an employer to inform employees about the hazards of chemical substances they are exposed to occupationally, that standard does not apply to biological hazards such as TB. Consequently, it is OSHA's intent in this paragraph to assure that employees will receive adequate warning through labels, signs, and training so that the employee understands the hazard and can take steps to eliminate or minimize his or her exposure to tuberculosis.

Paragraphs (h)(1) and (h)(2) of the proposed standard for tuberculosis provide the specific labeling and sign requirements that are to be used to warn employees of hazards to which they are exposed. The requirements for labels and signs are consistent with section 6(b)(7) of the OSH Act, which prescribes the use of labels or other appropriate forms of warning to apprise employees of occupational hazards. As noted in paragraphs (c)(2)(v), (d)(3), and (d)(5) above, settings where home health care and home-based hospice care are provided are not required to have engineering controls and, therefore, the signs and labeling would not be required in these cases.

Labels

Paragraph (h)(1)(i) requires that air systems that may reasonably be anticipated to contain aerosolized *M. tuberculosis* must be labeled at all points where ducts are accessed prior to a HEPA filter and at duct access points, fans, and discharge outlets of non-HEPA filtered direct discharge systems. The label must state ''Contaminated Air—Respiratory Protection Required.'' The provision for labeling of air ducts that may reasonably be anticipated to contain aerosolized *M. tuberculosis*, with the proposed hazard warning, is supported by the CDC in its discussion of HEPA filter systems. This discussion states:

> Appropriate respiratory protection should be worn while performing maintenance and testing procedures. In addition, filter housing and ducts leading to the housing should be labeled clearly with the words ''Contaminated Air'' (or a similar warning). (Ex. 4B)

The intent of this provision is to assure that employees who may be accessing these systems for the purposes of activities such as maintenance, replacement of filters, and connection of additional ductwork are warned of the presence of air that may contain aerosolized *M. tuberculosis* so that appropriate precautions can be taken. Consequently, labels are to be placed at all points where these systems are accessed.

In situations where air that may reasonably be anticipated to contain aerosolized *M. tuberculosis* is discharged directly to the outside, the exhaust outlets are also to be labeled. This is especially important since these outlets will most likely be at a remote location from the contaminated air source. Employees working in these locations would have no warning of the hazard if these ducts were not labeled. In addition, a number of exhaust outlets from a variety of sources may be present in an area (e.g., a hospital roof). In such situations, labeling also serves to distinguish contaminated air exhaust outlets from others in the vicinity.

The proposed provision does not require that a symbol (e.g., ''STOP'' sign) be included on the duct labels. OSHA believes that, in many situations, the label will be stenciled onto the duct, similar to the labeling used on other piping and duct labels currently being employed in some of these facilities. In addition, the group of workers accessing ducts will likely be a well-defined, skilled group that can be trained to recognize the text's warning. However, OSHA seeks comment on whether a symbol on duct labels is necessary and any information regarding the current use of such symbols.

Paragraph (h)(1)(ii) requires that clinical and research laboratory wastes that are contaminated with *M. tuberculosis* and are to be decontaminated outside of the immediate laboratory must be labeled with the biohazard symbol or placed in a red container(s). This provision is intended to assure that employees are adequately warned that these containers require special handling. In addition, the label or color-coding serves as notice that certain precautions may be necessary should materials in the container be released (e.g., a spill). This provision closely follows the recommendations outlined in the CDC-NIH publication ''Biosafety in Microbiological and Biomedical Laboratories'' (Ex. 7–72) and is in accordance with the labeling requirements of paragraph (e)(2)(i)(D), Clinical and Research Laboratories, of this section.

Signs

Paragraph (h)(2) contains the provisions relative to the posting of warning signs in areas where employees may be exposed to droplet nuclei or other aerosols of *M. tuberculosis*. More specifically, paragraph (h)(2)(i)(A) requires that signs be posted at the entrances to rooms or areas used to isolate an individual with suspected or confirmed infectious TB. The term ''rooms or areas'' is used in order to expand the requirement beyond the AFB isolation room or area. Throughout the course of a day various employees may enter such rooms or areas in order to carry out their duties. These employees can include physicians, nurses, respiratory therapists, housekeepers, and dietary workers. Posting a sign at the entrance of those rooms or areas where an individual with suspected or confirmed infectious TB is isolated serves to warn employees that entry into the room or area requires that certain precautions be taken. In addition, the employer may have implemented a program to minimize the number of employees who enter such rooms or areas. In this case, the sign serves as notice that entry may not be permitted for a particular employee or group of employees. As an additional public health benefit, such signs will also provide warning to visitors or family members who may be entering the area and are unaware of the hazard.

Paragraph (h)(2)(i)(B) requires that signs be posted at the entrances to areas where procedures or services are being performed on an individual with suspected or confirmed infectious TB. Although it is critically important to provide appropriate warning to employees who may inadvertently enter an isolation room, other areas of the facility are of concern as well. Special treatment areas, such as bronchoscopy suites, respiratory therapy areas where cough-inducing procedures are performed, or radiology examination rooms may, at one time or another, be occupied by an individual with suspected or confirmed infectious TB. When individuals with suspected or confirmed tuberculosis are occupying these areas, the area must have signs placed at the entrances in order to warn employees of the hazard.

The risk of exposure to aerosolized *M. tuberculosis* also exists in clinical and research laboratories where specimens, cultures, and stocks containing the bacilli are present. Therefore, paragraph (h)(2)(i)(C) requires that a sign be posted at the entrance to laboratories where *M. tuberculosis* is present. Posting of such a sign is consistent with the recommendations of the CDC/NIH publication ''Biosafety in Microbiological and Biomedical Laboratories'' (Ex. 7–72) and is in accordance with the sign posting requirement of paragraph (e)(2)(ii)(E), Clinical and Research Laboratories, of this section.

Even though a suspected or confirmed infectious individual is no longer present in a room or area, the droplet nuclei generated by that individual may continue to drift in the air. Consequently, the air in the room or area presents a risk of TB infection until the droplet nuclei are removed. With this in mind, paragraph (h)(2)(ii) requires that when an AFB isolation room or area is vacated by an individual with suspected or confirmed infectious TB, unless the individual has been medically determined to be noninfectious, the sign shall remain posted at the entrance until the room or area has been ventilated according to CDC recommendations for a removal efficiency of 99.9%, to prevent entry without the use of respiratory protection [The rationale for specifying this removal efficiency has been discussed previously under paragraph *(d), Work Practices and Engineering Controls*]. This provision is supported by the CDC's current recommendations for tuberculosis control (Ex. 4B).

The CDC has published guidelines regarding the length of time for such sanitation of the room air based upon the air exchanges per hour (see Appendix C of this section). Requiring that the sign remain posted until the room or area is adequately ventilated will assure that unprotected employees do not inadvertently enter while an infection risk is still present.

Until such time as the room or area has been adequately ventilated, employees entering the area must wear respiratory protection. This paragraph is designed to address the situations where employees will be entering or using a room or area previously occupied by an individual with suspected or confirmed infectious TB before the room or area has been satisfactorily ventilated. For example, when an infectious tuberculosis patient is discharged from a facility and the room is needed for an incoming new patient, certain housekeeping and maintenance functions need to be done between patient occupancies. Employees who must perform the tasks required to prepare the room for the next patient must wear respiratory protection until such time as the room has been adequately ventilated, based upon the CDC criteria. Obviously, if the room was previously occupied by an individual with suspected infectious TB and that individual is medically determined to be noninfectious, it would not be necessary to ventilate the room to remove *M. tuberculosis* nor to continue to post a sign at the entrance to the room since there would be no tuberculosis bacilli present.

OSHA has given much consideration to what sign should be required for posting outside of isolation rooms or areas and for areas where procedures or services are performed on individuals with suspected or confirmed infectious TB. The purpose of the sign is to convey a uniform warning along with the necessary precautions to be used for the particular situation.

The sign recommended by the CDC in 1983 in their ''CDC Guidelines for Isolation Precautions in Hospitals'' (Ex. 7–112) read ''AFB Isolation'' and then listed the requirements for entry. However, the instructions on the CDC sign are different from OSHA's requirements. For example, the sign instructed workers that ''Masks are indicated only when patient is coughing and does not reliably cover mouth'', a recommendation that is currently outdated and no longer recommended by CDC. The document contained another sign for ''Respiratory Isolation'' but this sign was designed for use with a number of respiratory hazards (rubella, meningococcal meningitis, chickenpox) that are not addressed in OSHA's proposed standard. Neither the 1990 CDC tuberculosis guidelines (Ex. 3–32) nor the 1994 CDC tuberculosis guidelines (Ex. 4B) provided help with this issue. OSHA also considered using a sign having the words ''AFB Isolation'' however, there is some concern that ''AFB Isolation'' could compromise patient confidentiality. For example, that sign outside of a treatment area or isolation room would allow members of the public or employees with no ''need to know'' to discern the potential diagnosis of the individual being isolated.

In addition, OSHA was unable to find uniform recommendations about signs in sources outside of the CDC. A number of facilities use signs to warn employees of the hazard of TB, but these signs vary widely and often had been developed for a particular facility. Thus, facilities that were using TB warning signs did not appear to be universally applying a specific sign.

The Agency does not believe, however, that development of a sign should be left to individual employers since this could lead to a variety of signs that may not provide adequate warning of the hazard. In the work settings covered by the proposal, there are many employees who move from facility to facility or even from industry to industry. In fact, a substantial number, like contract nurses, will work in several facilities at one time. A universal sign will enable these employees to recognize the hazard wherever it occurs and then take proper precautions. The issue of whether OSHA should specify colors that must be included on the sign was raised at TB stakeholder meetings. OSHA realizes there is a part of the population, perhaps as high as 10% of all men, that is color blind and that at some work sites some colors have been employed that are different from the red that OSHA proposes be used. However, stakeholders, particularly those whose jobs took them to several different work sites, urged OSHA to require a standardized sign and, of those who considered the issue, there was general agreement that the red on the familiar ''stop'' sign was appropriate. OSHA has preliminarily concluded that the colors required provide needed warning even though not all employees (e.g., those who are color blind) may benefit from them, and that the colors chosen are consistent with conventions on health signage. The Agency has developed a sign that it believes will provide appropriate warning and be easily recognizable. Failing to find either a guideline recommendation or a generally accepted community standard regarding what sign should be placed at the entrances to these areas, OSHA looked to generic, broad-based sources for symbols which would be easily identifiable, understandable to workers who were not able to read well or are non-English speaking, and simple to construct.

In paragraph (h)(2)(iii), therefore, OSHA is proposing that a ''STOP'' sign with the accompanying legend, ''No Admittance Without Wearing A Type N95 Or More Protective Respirator'', meets these criteria. The sign is easily recognizable, requires a simple color scheme, and should be understandable to employees with minimal training.

OSHA is seeking information on the effectiveness of the proposed sign to warn workers of the presence of a hazard, as well as information on other signs that may be more effective. Please be specific when providing information, keeping in mind the wide variety of work sites where signs will be needed. Where an alternative is being proposed, please enclose a model or drawing as well as the rationale for believing that it will be more effective than OSHA's proposed sign.

Paragraph (h)(2)(iv) requires that signs at the entrances of clinical or research laboratories and autopsy suites where procedures are being performed that may generate aerosolized *M. tuberculosis* include the biohazard symbol, name and telephone number of the laboratory director or other designated responsible person, the infectious agent designation

''*Mycobacterium tuberculosis*'', and special requirements for entering the laboratory or autopsy suite. This provision has been taken directly from the CDC/NIH publication ''Biosafety in Microbiological and Biomedical Laboratories'' (Ex. 7–72). As previously discussed, the purpose for this sign is to warn employees of the potential TB hazard and inform them of precautions that must be taken to prevent exposure.

Information and Training

It is OSHA's position that employees must understand the nature of the hazards in their workplace and the procedures to follow in order to eliminate or minimize their risks of exposure to these hazards. (Exs. 4–B, 7–169, 7–170, 7–61, 7–64) In the case of *M. tuberculosis*, employee exposures may result in a TB infection, which may ultimately result in disease and even death. The provisions in paragraph (h)(3) of this proposed standard set forth the training that each employer must provide to his or her employees. OSHA believes that effective training is a critical element in any occupational safety and health program. In this proposed standard, the employer would be required to provide training for each employee covered by the scope of the standard.

Paragraph (h)(3)(i) requires that employers assure that each employee with occupational exposure participates in training, which must be provided at no cost to the employee and be made available at a reasonable time and place. Since appropriate training is considered to be critical in assuring employee protection, the employer is responsible for making sure that each employee with occupational exposure participates in the training program. Having the employee pay in some manner for all or part of the training or requiring the employee to attend training at an unreasonable time and place would be a disincentive to participation. If training cannot feasibly be provided during work hours, employees are to be paid for training scheduled outside of normal working hours.

In view of the importance of training, OSHA is proposing that it be provided at several particular points in time. (Exs. 7–169; 4–B) More specifically, paragraph (h)(3)(ii) requires that training be provided: (A) before initial assignment to tasks where occupational exposure may occur, for those employees without previous occupational exposure; (B) within 60 days after the effective date of the final standard, for those employees who have occupational exposure at the time of the standard's promulgation; and (C) at least annually thereafter, unless the employer can demonstrate that the employee has the specific knowledge and skills required under paragraph (h)(3)(vii). The employer must provide re-training to an employee in any of the topic(s) in paragraph (h)(3)(vii) in which that employee cannot demonstrate the necessary knowledge and/or skill. This approach to training frequency assures that employees entering jobs with occupational exposure will be fully trained before exposure occurs. In addition, employees who are already working in jobs with occupational exposure at the time of the standard's promulgation will receive training and must become knowledgeable in all of the required aspects of the standard (e.g., employer's exposure control plan, medical surveillance program, warning signs and labels) within a short period of time.

Annual re-training reinforces the initial training and provides an opportunity to present new information that was not available at the time of initial training. The Agency recognizes that, as a result of training previously provided by the employer, employees may possess some of the knowledge and skills listed in the training topics in paragraph (h)(3)(vii). Consequently, OSHA is proposing that re-training be provided annually unless the employer can demonstrate that the employee has the specific knowledge and skills required by this paragraph. The employer must provide re-training to an employee in any topic(s) in paragraph (h)(3)(vii) in which the employee cannot demonstrate specific knowledge and skills.

An employee with occupational exposure to TB who moves to a job with another employer that also involves occupational exposure to TB would not need to meet all of the initial training requirements. In such instances, the Agency has determined that the employee's prior training in the general topics required by the standard (e.g., the general epidemiology of tuberculosis, the difference between tuberculosis infection and tuberculosis disease) would remain relevant in the new work setting and that the new employer need not re-train in these topics. However, the employee would not possess knowledge of the topics required by the standard that are specific to the new employer's particular work setting (e.g., the new employer's exposure control plan and respiratory protection program and the means by which the employee could access the written plans for review). OSHA is proposing to permit limited ''portability'' of training, as noted in the standard. This note states that training in the general topics listed in paragraph (h)(3)(vii) that has been provided in the past 12 months by a previous employer may be transferred to an employee's new employer. However, the new employer must provide training in the site-specific topics listed in paragraph (h)(3)(vii) in accordance with the requirements of paragraph (h) (e.g., at no cost to the employee and at a reasonable time and place).

OSHA is aware that some employers have already established training for their occupationally exposed employees. (Ex. 7–169) In light of this, paragraph (h)(3)(iii) of the proposed standard requires only that limited training be conducted for those employees who already have received training on tuberculosis in the year preceding the effective date of the standard. The additional training would only have to address those provisions of the standard not previously covered in the earlier training.

The requirement for annual training within one year of the employee's previous training, in paragraph (h)(3)(iv), assures that each employee receives training within 12 calendar months of his or her last training. Annual training is not based on a calendar year; that is, training will not be permitted to be provided to an employee in January of one year and in December of the following year, essentially a 23-month span between training sessions. Employers may establish schedules for training around this requirement.

Also, paragraph (h)(3)(v) stipulates that the employer must provide additional training whenever changes in the occupational environment, such as modification of tasks or procedures or institution of new tasks or procedures, affect the employee's occupational exposure to *M. tuberculosis*. This provision will assure that employees remain apprised of any new exposure hazards and the precautions necessary to protect themselves from exposure. This additional training does not need to entail a complete reiteration of the annual training, but may be limited to addressing the new sources of potential exposure.

The proposed standard requires that training material be used that is appropriate in content and vocabulary to the educational level, literacy and language of employees. Employees must be able to comprehend the information being conveyed in order for it to be useful. Therefore, the employer has the responsibility for assuring that the training is provided in an understandable manner to the audience being addressed. This provision would

assure that employees, regardless of their educational or cultural background, will receive adequate training.

Paragraph (h)(3)(vii) of the proposed standard contains the specific elements that would comprise a minimum training program. (Exs. 4–B; 7–169; 7–64) The provisions for employee training are performance oriented, stating the categories of information to be transmitted to employees and not the specific ways that this is to be accomplished. This assures that important information is communicated to employees about the nature of this occupational hazard while allowing employers the most flexible approach to providing training. OSHA has set forth the objectives to be met and the intent of training. The specifics of how the employer assures that employees are made aware of the hazards in their workplace and how they can help to protect themselves are left up to the employer who is best qualified to tailor the training to the TB hazards in his or her workplace.

The proposed standard would require the employer to explain a number of particular topics in the training session(s). Paragraph (h)(3)(vii)(A) requires the employer to provide an explanation of the contents of this standard and the location of an accessible copy of the regulatory text and appendices to this standard. This enables the employee to have access to the standard and to become familiar with its provisions. It is not necessary for the employer to provide each employee with a copy of the standard; it is sufficient for the employer simply to make a copy accessible. For example, a copy of the standard could be posted in a location where it could be readily and easily viewed by employees.

An important element in the training involves an overview of the epidemiology of tuberculosis, the pathogenesis of the disease and an explanation of various aspects of risk to employees. (Ex. 4B) More specifically, paragraph (h)(3)(vii)(B) requires that the training include an explanation of: the general epidemiology of tuberculosis, including multidrug-resistant TB and the potential for exposure in the facility; the signs and symptoms of TB, including the difference between TB infection and TB disease; the modes of transmission of tuberculosis, including the possibility of reinfection in persons with a positive tuberculin skin test; and the personal health conditions that increase an employee's risk of developing TB disease if infected.

Since the employer can tailor the training to the needs of his or her employees, the training program will likely be more technical for some audiences and less technical for others. The general goal of this paragraph is to assure that each employee being trained understands what tuberculosis is, how it is spread, and possible risks that may affect the employee.

Employees need to be able to recognize symptoms associated with TB disease. (Ex. 4B) The employee must understand that certain symptoms (e.g., a persistent cough lasting 3 or more weeks, bloody sputum, night sweats, anorexia, weight loss, fever) may be related to TB. In addition, information on non-occupational risk factors that place employees at increased risk of developing tuberculosis disease following an infection permits those individuals at increased risk to make informed decisions about their employment situations.

Paragraph (h)(3)(vii)(C) requires an explanation of the employer's exposure control plan and respiratory protection program. Employees must also be informed about what steps they need to take to review the written plans, if they so desire.

Paragraph (h)(3)(vii)(D) requires the employer to train employees regarding the tasks and other activities that may involve occupational exposure to tuberculosis. Employees must be made aware of those job duties which may expose them to tuberculosis. For example, although certain health care professionals may easily recognize the hazard involved in transporting a person with infectious TB, the staff of a correctional facility may not. On the other hand, some health care professionals may not immediately recognize that their mere presence in a room where an individual with suspected or confirmed infectious TB is being X-rayed presents an exposure risk and necessitates wearing a respirator. All occupationally exposed employees need training that will enable them to recognize those activities that put them at risk of exposure.

Paragraph (h)(3)(vii)(E) of this section requires employers to train employees regarding both the uses and limitations of various control measures, specifically those used at the employees' worksite. Exposed employees must be familiar with the employer's tuberculosis policies and procedures in order for them to be properly implemented. Control of exposure frequently involves using a variety or combination of engineering controls, administrative controls, work practice procedures and personal protective equipment. To assure that employees will be able to identify and implement methods of reducing occupational exposure to tuberculosis, they must understand how these controls are applied in their work sites and the limitations thereof. With this understanding, employees will be more likely to use the appropriate control for the situation at hand and to use it correctly. For example, employees must be able to recognize the labels and signs used to identify rooms or areas where suspected or confirmed infectious individuals are present so that they can take appropriate precautions before entering. Understanding of the limitations of control measures will also enable employees to recognize when inappropriate or inadequate control measures have been taken and increases the likelihood that they will report such situations.

Training must be relevant to the specific site where the employee will be working. Each employee must know, for example, the procedures used in his or her particular facility to identify suspected infectious TB cases, where respiratory protection is kept, and what engineering controls are in place within the facility. This training is particularly important for workers who move between several facilities in the course of their work, for example, ''leased'' personnel, part-time employees, ''moonlighters'', or contractors.

The provision covering the selection, types, proper use, location, removal and handling of respiratory protection, paragraph (h)(3)(vii)(F), is particularly important because many of the employees and employers proposed to be covered by the tuberculosis standard may not be accustomed to the use, selection, and upkeep of respiratory protection. Consequently, training on aspects such as the necessity for respiratory protection, the appropriate type of respiratory protection, where to obtain it, and its proper use, fit, and the general upkeep is necessary to assure the effectiveness of respirator use. (Ex. 7–64)

OSHA believes that employees who have a clear understanding of the medical surveillance program (its purpose, methodology, and the significance of the results of examinations and tests), will be much more likely to participate in that program. Therefore, paragraph (h)(3)(vii)(G) requires that the training include an explanation of the employer's medical surveillance program, including the purpose of tuberculin skin testing, the importance of a positive or negative skin test result, anergy testing, and the importance of participation in the program. This increased participation by trained

employees helps the employee to identify changes in his or her personal health status and also aids the employer in assessing the effectiveness of his or her TB control program.

Each employee must understand the actions to be taken if an occupational exposure occurs as well as what is available to them regarding appropriate medical treatment, prophylaxis, and post exposure follow-up in order for the employee to lessen the chance of developing active disease. Therefore, paragraph (h)(3)(vii)(H) would require an explanation of the procedures to follow if an exposure incident occurs, including the method of reporting the incident, an explanation of the medical management and follow-up that the employer is required to provide, and the benefits and risks of drug prophylaxis. In addition, the employee must be provided with an explanation of the procedures to follow if the employee develops signs or symptoms of tuberculosis disease [paragraph (h)(3)(vii)(I)]. In this way, an employee who notes the signs or symptoms of personal disease development will be aware of the appropriate steps to take, thereby speeding initiation of medical evaluation. Quick evaluation protects the employee, co-workers, and the public.

In paragraph (h)(3)(viii), the proposed standard mandates that the person conducting the training must be knowledgeable in the subject matter as it relates to the specific workplace being addressed. OSHA believes that a variety of persons are capable of providing effective training to employees. OSHA has approached this section of the proposed standard in much the same way as the trainer requirements were addressed in the standard for Occupational Exposure to Bloodborne Pathogens. That is, a knowledgeable trainer is one who is able to demonstrate expertise in the area of the occupational hazard of tuberculosis and is familiar with the manner in which the elements of the training program relate to the particular workplace.

A number of resources are available through the Centers for Disease Control and Prevention and professional organizations such as the American Lung Association and the American Thoracic Society that can be used to educate trainers and prepare them for this task. In addition, specialized training courses in the area of tuberculosis control can also assist in educating trainers (Ex. 7–189).

In addition to general knowledge of the subject matter, it is important that the trainer be able to instruct the participants in site-specific features of the Exposure Control Plan that will reduce their risk in the particular facility. This benefits not only employees within the facility but also provides temporary employees with the information needed to protect themselves against exposure while working in the facility. For example, workers who have received general training by their employer (e.g., a personnel staffing agency) will also receive training about the facility where they will actually perform their duties (e.g., a specific hospital).

An important component of an effective learning experience is the opportunity for the learner to interact with the trainer for the purposes of asking questions and obtaining clarification. Paragraph (h)(3)(ix) would require that the employer provide employees with this opportunity as part of the training program. The trainer must be available at the time that the training takes place. OSHA would expect that in most instances, the individual who would provide answers to the employee's question would be physically present when the employee is trained. The Agency does recognize, however, that there may be some instances where this is not possible. In these cases, it would be acceptable for the employee to ask questions by telephone.

An employer would not be expected to train employees in site-specific topics that are not applicable to the employer's work setting. For example, if a facility was not required by the standard to utilize engineering controls, the employer would not be responsible for training his or her employees about the various aspects of engineering controls.

OSHA believes that the information and training requirements incorporated into this proposed standard are needed to inform employees about the hazard of tuberculosis and to provide employees with an understanding of the degree to which they can minimize the health hazard. Training is essential to an effective overall hazard communication program and serves to explain and reinforce the information presented to employees on signs and labels. These forms of information and warning will be meaningful only when employees understand the information presented and are aware of the actions to be taken to avoid or minimize exposure.

OSHA seeks comment on the proposed content of the training program and requests that model TB training programs be submitted to the docket, particularly those designed for audiences whose participants may have language difficulties or have no health care background, and those that have been judged to be successful in communicating information to employees. It is OSHA's intent, upon publication of the final standard, to include information on training programs in compliance guides to be developed for small entities.

Paragraph (i) Recordkeeping

This proposed standard requires employers to keep records related to TB, including medical surveillance and training records for all employees with occupational exposure and engineering control maintenance and monitoring records. OSHA has made a preliminary determination that, in this context, medical and training records are necessary to assure that employees receive appropriate information on hazards and effective prevention and treatment measures, as well as to aid in the general development of information on the occupational transmission of TB. Specifically, OSHA believes that maintenance of medical records is essential because documentation is necessary to ensure proper evaluation of an employee's infection status and for prompt and proper healthcare management following an exposure incident. OSHA has also preliminarily determined that maintenance and monitoring records for engineering controls are necessary for two reasons: to enable the employer to know that the control methods remain in good working order so as to assure their effectiveness and to aid the Agency in enforcement of the standard.

In paragraph (i)(1), OSHA proposes to require employers to establish and maintain a medical record in accordance with 29 CFR 1910.1020 for each employee with occupational exposure to TB. The record must include: (A) The name, social security number, and job classification of the employee; (B) A copy of all results of examinations, medical testing, including the employee's tuberculin skin test status; and follow-up procedures required by paragraph (g); (C) The employer's copy of the physician's or other licensed health care professional's written opinion as required by paragraph (g)(7); and (D) A copy of the information provided to the physician or other health care professional required by paragraph (g)(6). The information that must be included in the medical record is necessary for the proper evaluation of the employee's infection status and management of occupational exposure incidents. This record will aid OSHA in enforcing the standard and the information therein, when analyzed, will further the development of health

data on the causes and prevention of occupational transmission of TB. Similar provisions for collection and retention of such information have been included in other OSHA health standards including, most recently, Bloodborne Pathogens (29 CFR 1910.1030) and Cadmium (29 CFR 1910.1027).

In paragraph (i)(1)(iii), OSHA is proposing to require that the employee medical records be kept confidential and not be disclosed or reported to anyone without the employee's express written consent except as required by section i or as may be required by law. In nearly every health standard rulemaking, employees have told the Agency that keeping medical records confidential is extremely important to them. Employees stated that, without assurance of confidentiality, they would be reluctant to participate in medical surveillance, a predicament that would be detrimental to their health and could affect health and safety conditions in the workplace. During the Bloodborne Pathogens rulemaking, confidentiality of medical records was a major issue due to the nature of the diseases addressed. Of particular concern was keeping the medical records from being disclosed to the employer. It was explained in the Bloodborne Pathogens standard and is applicable here that such confidentiality can be accomplished by having the records kept by the physician or other licensed health care provider at the expense of the employer. In those cases where the employer is the health care provider, the records can be maintained separately from other employee records so that disclosure can be strictly limited to the physician or other licensed health care professional and his or her staff who are responsible for the medical management of the employee. It was pointed out in the preamble to the Bloodborne Pathogens standard, and bears repeating here, that the confidentiality provisions in the proposed standard are reiterations of existing standards of conduct in the health care professions and that the OSHA requirements do not abridge, enlarge or alter existing ethical or statutory codes (56 FR 64170). This section of the proposal requires that medical records be disclosed to the Assistant Secretary or the Director (of NIOSH) and as may be required by law, which means that this proposed standard would not prevent employers from reporting TB cases to federal, state, or municipal health departments where that reporting is required by law.

Paragraph (i)(1)(iv) proposes to require that medical records be maintained in accordance with 29 CFR 1910.1020 for at least the duration of employment plus 30 years. The Access to Medical Records Standard contains an exception to the 30-year requirement that provides that the medical records of an employee who has worked less than one year must be maintained throughout his or her employment, but need not be retained afterwards as long as they are given to the employee upon termination of employment. Maintaining the records for the duration of employment serves several purposes: the records can provide valuable information to the employee's healthcare provider; the records enable the employer to know that employees are benefitting from regular surveillance and timely intervention following occupational exposure to TB; analysis and aggregation of the records can provide insight into the causes and consequences of occupational exposure to TB; and, the records will aid in the enforcement of the standard. Requiring the records to be kept 30 years beyond employment is necessary because TB can have a long incubation period, with disease often appearing only many years after initial infection. This retention time is also consistent with other OSHA health standards (See for example Benzene, 29 CFR 1910.1028; Bloodborne Pathogens, 29 CFR 1910.1030; Ethylene Oxide, 29 CFR 1910.1047).

In paragraph (i)(2), OSHA proposes to require employers to record TB infection and disease in accordance with 29 CFR 1904, Recording and Reporting Occupational Injuries and Illnesses, and 29 CFR 1960, the equivalent requirement for Federal Agency programs. This should not be an unfamiliar requirement to employers because occupational TB infections and disease must be reported in accordance with 29 CFR 1904 and 29 CFR 1960, as directed by current OSHA enforcement policy (Ex. 7–1).

In paragraph (i)(3), OSHA proposes to require training records, which include: (A) The dates of the training sessions; (B) The contents or a summary of the training sessions; (C) The names and qualifications of persons conducting the training; and (D) The name and job classification of all persons attending the training sessions. This requirement is consistent with other OSHA standards, particularly Bloodborne Pathogens, and it represents the minimum amount of information an employer, an employee, or an OSHA compliance officer would need in order to determine when and what training had been provided, who administered it and who attended. Additionally, such a record is an invaluable aid to the employer when evaluating his or her training program.

OSHA proposes, in paragraph (i)(3)(ii) to require that training records be maintained for three years beyond the date the training occurred. The Agency anticipates that employers will not have difficulty maintaining the records for three years because the information to be included is not extensive and many employers are already keeping training records three years as required by other OSHA standards (e.g., Bloodborne Pathogens, 29 CFR 1910.1030). Moreover, these records are not required to be kept confidential and so may become part of an employee's personnel file or part of a larger file, at the discretion of the employer.

In paragraph (i)(4), OSHA proposes to require engineering control maintenance and monitoring records be kept that include: (A) Date; (B) Equipment identification; (C) Task performed; and (D) Sign-off. The performance monitoring records must include: (A) Date and time; (B) Location; (C) Parameter measured; (D) Results of Monitoring; and (E) Sign-off. Only two of these items will require more than a few words or numbers to record; the two items that require more extensive information are the maintenance task performed and the results of the performance monitoring. Where the employer has not already developed a method for recording the task performed, the maintenance person can list the tasks or use a previously prepared check-list. The results of performance monitoring can be recorded in the same way or another way that meets the needs of the particular workplace so long as it includes all of the information required by the paragraph. OSHA believes that the information in these records is the usual data that are generated by persons maintaining and servicing equipment so that the status of the equipment and its effectiveness can be known for a given time. The information is also useful in determining when further servicing is needed.

Proposed paragraph (i)(4)(iii) requires engineering control maintenance and monitoring records to be maintained for three years. The three year period is a reasonable period of time and it will enable the employer to develop and sustain a proper maintenance program and to track the effectiveness of the controls. Moreover, the records will aid the OSHA compliance officer in enforcing the standard's requirements for engineering controls.

Availability of medical records is specified in section 8(c) of the Act. In paragraph (i)(5) of this standard, OSHA

proposes to restrict the availability of employee medical records while making employee training records and engineering control and monitoring records generally available upon request. Medical records must be provided to the subject employee, to anyone having written consent from the employee, to the Director and to the Assistant Secretary in accordance with 29 CFR 1910.1020, which sets forth the procedures that will protect the privacy concerns of the employees. This paragraph does not affect existing legal and ethical obligations concerning maintenance and confidentiality of employee medical records. An employer's access is governed by existing federal, state and local laws and regulation. This standard, like Bloodborne Pathogens (29 CFR 1910.1030) and other OSHA standards, limits employer access to confidential information while allowing the employer access to the information needed to make appropriate decisions relative to his or her medical surveillance program. For example, paragraph (g)(7)(ii) limits the information that can be included in the physician's or other licensed health care professional's written opinion and paragraph (g)(7)(iii) requires that other medical diagnoses or findings be kept confidential. There is no language in this proposed standard that grants an employer access to the confidential information in an employee's medical file. OSHA illness and injury records are accessible under 29 CFR 1904 and 29 CFR 1960, as appropriate, to the facility. In this proposal, as in OSHA's other health standards, training records and engineering control maintenance and monitoring records are to be provided upon request to the employees, their representatives, the Director and the Assistant Secretary. Employers should not have difficulty complying with this provision because most will have experience with such recordkeeping from other standards. There are no confidentiality issues raised by these records.

In paragraph (i)(6), an employer who goes out of business is required to transfer medical records as set forth in 29 CFR 1910.1020(h) and 29 CFR 1904, which address the transfer of medical records. Specifically, medical records must be transferred to a successor employer who must accept them and keep them in accordance with the requirements of 29 CFR 1910.1020. In the event the employer ceases to do business and there is no successor employer, the employer is required to notify the Director, at least three months prior to disposal of the records, and transmit them to the Director if required by the Director to do so. This is consistent with other health standards and ensures that a successor employer (and the employees) can benefit from the information contained in the records. The reason the records are transferred (if requested) to the Director of NIOSH is that NIOSH has a vested interest in maintaining records of occupational injuries and illnesses and is in an excellent position to decide how the records can be best used to be of value to the exposed employee, subsequent employees in the field and OSHA. At NIOSH, the records remain confidential as required by 29 CFR 1910.1020(e). Thus, only the employee or his or her representative with the permission of the employee retains access to the medical records transferred to NIOSH.

Paragraph (j) Definitions

Acid-Fast Bacilli (AFB) means bacteria that retain certain dyes after being washed in an acid solution. Most acid-fast organisms are mycobacteria. Smears of sputum samples and other clinical specimens may be stained with dyes to detect acid-fast mycobacteria such as *M. tuberculosis.* However, AFB smear tests cannot distinguish one type of mycobacteria from another. Therefore, as noted by CDC, when AFB are seen on a stained smear of sputum or other clinical specimens, a diagnosis of TB should be suspected; however, the diagnosis of TB is not confirmed until a culture is grown and identified as *M. tuberculosis* (Ex. 4B).

Accredited Laboratory for purposes of this standard means a laboratory that has participated in a quality assurance program leading to a certification of competence administered by a governmental or private organization that tests and certifies laboratories. Under the medical surveillance provisions of the proposed standard, paragraph (g)(1)(iv) requires that all laboratory tests required by the standard be conducted by an accredited laboratory. This definition makes clear OSHA's intent about the type of laboratory that would be required to conduct these types of tests.

The term *AFB Isolation Room or Area* refers specifically to the rooms or areas where individuals with suspected or confirmed infectious TB are isolated. For purposes of this standard this term includes, but is not limited to, rooms, areas, booths, tents or other enclosures that are maintained at negative pressure relative to adjacent areas in order to control the spread of aerosolized *M. tuberculosis.* Such rooms or areas are able to contain droplet nuclei through unidirectional airflow into the room (i.e., negative pressure). A definition of negative pressure is presented below and a more detailed explanation can be found in the Summary and Explanation of paragraph *(d), Work Practices and Engineering Controls.*

Air purifying respirator means a respirator that is designed to remove air contaminants from the ambient air or air surrounding the respirator. Air purifying respirators remove particular contaminants (e.g., particulates, organic vapors, acid gases) from the ambient air by drawing the air through appropriate filters, cartridges, of canisters.

Anergy means the inability of a person to react to skin test antigens (even if the person is infected with the organism(s)tested because of immunosuppression. More specifically, an anergic individual's immune system has become so compromised that it is unable to mount a sufficient reaction to the test organism. Because of their inability to respond immunologically, persons with anergy will have a negative tuberculin skin test even if they are infected with *M. tuberculosis.* Therefore, as noted by the CDC, it may be necessary to consider other epidemiologic factors (e.g., the proportion of other persons with the same level of exposure who have positive tuberculin skin test results and the intensity or duration of exposure to infectious TB patients that the anergic person experienced) when making a determination as to whether that anergic individual has been infected with *M. tuberculosis* (Ex. 4B). As discussed under paragraph (g)(2)(iii), Medical Surveillance, tuberculin skin testing is to include anergy testing when the physician or other licensed health care professional, as appropriate, determines such testing is necessary. Knowing which individuals are anergic will help to determine those situations where information other than skin test status will need to be ascertained and considered in order to assess the likelihood of infection for exposed employees.

Assistant Secretary means the Assistant Secretary of Labor for Occupational Safety and Health, or designated representative, and is a definition consistent across all OSHA standards.

BCG (Bacille Calmette-Guerin) vaccine means a tuberculosis vaccine used in many parts of the world. Because of its variable efficacy and its impact upon tuberculin skin tests (i.e., making skin test interpretation more difficult), routine BCG vaccination is not currently recommended in the

United States (Ex. 7–50). However, many foreign countries still use BCG as part of their tuberculosis control programs, especially for infants (Ex. 7–72). Since individuals vaccinated with BCG may have a tuberculin skin test that cannot be distinguished reliably from a reaction caused by infection with *M. tuberculosis*, it is helpful to know whether an individual has been vaccinated with BCG and when such vaccination occurred. Thus, under the medical surveillance provisions of the proposed standard, the medical history is to include a history of BCG vaccination.

Cartridge or canister means a container with a filter, sorbent, or catalyst, or a combination of these items, that removes specific air contaminants from the air drawn through the container. With respect to this standard, respirators would be equipped with cartridges or canisters containing particulate filters.

Clinical laboratory has been defined for purposes of this standard as a facility or an area of a facility that conducts routine and repetitive operations for the diagnosis of TB, such as preparing acid-fast smears and culturing sputa or other clinical specimens for identification, typing or susceptibility testing. This definition is meant to apply to laboratories where routine diagnostic tests for TB are conducted as compared to research laboratories where *M. tuberculosis* may be cultured in large volumes or concentrated for research or commercial production. Clinical laboratories may be located within facilities such as hospitals or clinics, or they may be freestanding facilities.

Confirmed infectious tuberculosis (TB) means a disease state that has been diagnosed by positive identification of *M. tuberculosis* from body fluid or tissue through positive culture, positive gene probe, or positive polymerase chain reaction (PCR); and the individual is capable of transmitting the disease to another person. The disease state may be manifested as pulmonary or laryngeal TB or extrapulmonary TB if the infected tissue is exposed and could generate droplet nuclei.

As discussed under the definition for AFB, a positive AFB smear indicates only that an individual has an identifiable mycobacterium. The three methods listed here provide positive confirmation of *M. tuberculosis.* In addition, the definition states that the disease state must be capable of being transmitted to another person (i.e., infectious). This provision of the definition is to differentiate this state of the disease from other active forms of TB disease where the individual is not infectious. For example, an individual may contract active TB disease and become infectious. After adequate drug therapy has been initiated the individual may become noninfectious, at which point he or she cannot transmit the disease to other individuals. However, the individual, while no longer infectious, still has active disease and must continue treatment for several months because living bacilli are still in his or her body. The definition also states that the disease may be manifested as pulmonary or laryngeal TB or extrapulmonary TB if the infected tissue is exposed and could generate droplet nuclei. In most cases, it is the pulmonary or laryngeal forms of infectious TB that present a risk of infection for other individuals. This is due to the fact that tuberculosis bacilli in the pulmonary or laryngeal tracts may be easily dispelled when infectious individuals cough or speak. Other body sites infected with the bacilli, i.e., extrapulmonary TB, do not present an infection hazard in most cases because the bacilli are not capable of being dispelled outside the body. However, in some situations, such as a lesion or an abscess where the infected tissue is exposed, there may be a risk of transmission of disease when certain procedures are performed (e.g., tissue irrigation) that could generate droplet nuclei containing the bacilli.

Conversion means a change in tuberculin skin test results from negative to positive, based upon current Centers for Disease Control and Prevention (CDC) guidelines. Under paragraph (g), the employer is required to provide medical management and follow-up to employees who have converted to positive tuberculin skin test status (e.g., providing preventive therapy, if appropriate, and conducting follow-up investigations of circumstances surrounding the conversion). Since a number of specific actions are required of the employer as a result of a conversion, it is necessary that conversions be correctly identified. An important part of this identification is the interpretation as to whether an employee has a positive skin test response. As such, this definition states that the interpretation of the positive reaction should be based upon current CDC guidelines (Ex. 4B). It is not OSHA's intent to define what should constitute a positive reaction, but rather to assure that such determinations are made using currently accepted public health guidelines.

Director means the Director of the National Institute for Occupational Safety and Health, U.S. Department of Health and Human Services, or designated representative. Similar to the definition for Assistant Secretary, the definition for Director is consistent across OSHA standards.

Disposable respirator means a respiratory protective device that cannot be resupplied with an unused filter or cartridge and that is to be discarded in its entirety after its useful service life has been reached. In general, the facepiece of these respirators is constructed from the particular filter media of interest (e.g., particulate filter).

Exposure incident for purposes of this standard means an event in which an employee has been exposed to an individual with confirmed infectious TB or to air containing aerosolized *M. tuberculosis* without the benefit of all of the applicable exposure control measures required by this section. This definition is limited to those situations involving exposure to an individual with confirmed infectious TB or air originating from an area where a source of aerosolized *M. tuberculosis* is present; it does not include exposure to individuals with suspected infectious TB. OSHA has limited the definition in this way because several provisions in the proposed standard are triggered by the occurrence of an exposure incident. For example, under paragraph *(g), Medical Surveillance*, the employer is required to provide additional tuberculin skin testing to each affected employee and to investigate and document the circumstances surrounding each exposure incident to determine if changes can be instituted to prevent similar occurrences in the future. OSHA believes that it would be burdensome and unnecessary for the employer to conduct follow-up investigations for those occurrences where an employee's exposure is to an individual suspected of having infectious TB but for whom infectious disease is subsequently ruled out.

An example of an exposure incident is an employee entering an AFB isolation room or area occupied by an individual with confirmed infectious TB without the employee wearing appropriate personal respiratory protection equipment. This occurrence would not be defined under the standard as an exposure incident if the individual in the AFB isolation room had only suspected infectious TB. If the individual in AFB isolation room was later confirmed to have infectious TB, the employee entering the isolation room without appropriate respiratory equipment would then be considered to have had an exposure incident and the required medical management and follow-up provisions for an exposure

incident under paragraph *(g), Medical Surveillance,* would be required.

Another example of an exposure incident is a failure of engineering controls, e.g., the ventilation system in an AFB isolation room housing an individual with confirmed infectious TB malfunctioned, negative pressure was lost, and air containing *M. tuberculosis* was dispelled into the hall corridor, exposing unprotected employees. Although OSHA would consider this type of loss of negative pressure in an AFB isolation room to be an exposure incident, the Agency does not intend that each opening of the door to an AFB isolation room be considered an exposure incident, even though some loss of negative pressure may result when the door to an AFB isolation room is opened. As a practical matter, OSHA believes it would be infeasible to consider every instance that a door to an isolation was opened as an exposure incident. In addition, these losses of negative pressure are generally small, if doors are kept open only briefly for purposes of entry and exit and are kept closed at all other times while the room is in operation for TB isolation as required under the Work Practices and Engineering Controls paragraph (d)(5)(vi).

There is a significant difference in the meaning of the terms ''exposure incident'' and ''occupational exposure'' as they are used in this standard. This difference is discussed further under the definition of ''occupational exposure''.

Filter means a component used in respirators to remove solid or liquid aerosols from the inspired air. The filter is the medium that captures the aerosol, preventing it from passing through to the respirator wearer.

Fit factor is a quantitative measure of the fit of a particular respirator on a particular individual. Fit factor is derived from the ratio of the concentration of a challenge agent (or air pressure) outside of the respirator to the concentration of the test agent (or air pressure) inside the respirator.

High Efficiency Particulate Air (HEPA) Filter means a specialized filter that is capable of removing 99.97 percent of particles greater than or equal to 0.3 micrometer in diameter.

High-hazard procedures are those procedures performed on an individual with suspected or confirmed infectious tuberculosis in which the potential for being exposed to *M. tuberculosis* is increased due to the induction of coughing or the generation of aerosolized *M. tuberculosis.* Such procedures include, but are not limited to, sputum induction, bronchoscopy, endotracheal intubation or suctioning, aerosolized administration of pentamidine or other medications, and pulmonary function testing. They also include autopsy, clinical, surgical and laboratory procedures that may aerosolize *M. tuberculosis.* The procedures listed above present a high hazard because they are performed on individuals with suspected or confirmed infectious TB or on specimens or deceased individuals where *M. tuberculosis* may be present. For example, some of the procedures listed above, such as bronchoscopies and pentamidine administration, cause people to cough. For individuals with pulmonary TB, coughing will increase the likelihood that they will generate aerosols with a high concentration of droplet nuclei. In addition, certain autopsy procedures, such as cutting into a lung containing *M. tuberculosis,* and certain laboratory procedures, such as processing infected tissue samples with pressurized freezants, can generate aerosols containing droplet nuclei. In the absence of *M. tuberculosis,* these procedures would not be high-hazard. For example, endotracheal intubation on an individual who does not have suspected or confirmed infectious TB would not be considered a high-hazard procedure.

M. tuberculosis means *Mycobacterium tuberculosis,* the scientific name of the bacillus that causes tuberculosis.

Negative Pressure means the relative air pressure difference between two areas. A room that is under negative pressure has lower pressure than adjacent areas, which keeps air from flowing out of the room and into adjacent rooms or areas. Paragraph (d)(5)(i) of Work Practices and Engineering Controls requires that negative pressure be maintained in all AFB isolation rooms or areas, and paragraph (d)(4) requires that all high-hazard procedures be performed in such rooms or areas. Maintaining negative pressure in such rooms or areas helps to assure that droplet nuclei are contained and not spread to other areas of the facility where unprotected employees may be exposed. A further discussion of this principle can be found in the Summary and Explanation of paragraph *(d), Work Practices and Engineering Controls.*

Negative pressure respirator means a respirator in which the air pressure inside the facepiece is negative during inhalation with respect to the ambient air pressure outside the respirator. In a negative pressure respirator, the wearer's inhalation creates a drop in pressure inside the facepiece, consequently drawing outside air through the filter and into the respirator.

Occupational exposure is one of the key terms upon which the proposed standard rests. It contains the criteria that trigger application of the standard for employees in work settings covered under the scope of the standard as listed in paragraphs (a)(1) through (a)(8) and for employees providing the care and services listed in paragraphs (a)(9) and (a)(10). Although a variety of work settings and several specific types of work are covered within the scope of the standard, it is only employees who have ''occupational exposure'' in those work settings and who are providing the particular services that must be given the protection mandated by the standard. The exception to this is that an employer covered under paragraph *(a), scope,* must provide medical management and follow-up to other employees who have an exposure incident.

For purposes of this standard, occupational exposure means reasonably anticipated contact, which results from the performance of an employee's duties, with an individual with suspected or confirmed infectious TB or air that may contain aerosolized *M. tuberculosis.* An example of reasonably anticipated contact between an employee and an individual with suspected or confirmed infectious TB would be an admissions clerk working in a homeless shelter. In view of the high incidence of TB among the homeless, it can reasonably be anticipated that an employee screening people for admission into the shelter would have contact with a person with infectious TB during the performance of his or her job duties. Another, more obvious, example would be a bronchoscopist in a hospital that provides care for individuals with suspected or confirmed infectious TB. Others could include some physicians, nurses, paramedics and emergency medical technicians, health aides, prison guards, and intake workers in the facilities listed in paragraph (a) of this section. An example of an employee who would not be reasonably anticipated to have occupational exposure is an worker, in a covered facility, whose duties were limited to working in an area where suspected or confirmed TB patients or clients do not go and where the air would not contain aerosolized *Mycobacterium tuberculosis.* The risk of exposure for this employee is comparable to the exposure potential by the general population.

The term *occupational exposure* is used differently than the term *exposure incident* in the proposed standard. Occupational exposure is used to define

a condition of the employee's work and to identify which employees are affected in a way that can reasonably be anticipated, due to their job duties, to involve potential exposure to aerosolized *M. tuberculosis*, i.e., contact with an individual with suspected or confirmed infectious TB or with air that may contain aerosolized *M. tuberculosis.* The intent of the standard is to prevent exposure to aerosolized *M. tuberculosis;* therefore, certain proactive measures are required by the standard, e.g., training and medical surveillance, when occupational exposure is present. In order to provide these measures, it is necessary to identify which employees may be exposed *before* exposure occurs. The definition of ''occupational exposure'' is the basis for making this identification.

An *exposure incident,* on the other hand, is a discrete event in which it is known that an employee has had contact with aerosolized *M. tuberculosis,* i.e., with an individual with confirmed infectious TB or air containing aerosolized *M. tuberculosis.* The term ''exposure incident'' is used to define those occasions when certain reactive measures are required by the standard, such as medical management and follow-up. It is exposure to an individual with confirmed infectious TB that matters, since it is not necessary to take reactive measures after being exposed to an individual with suspected infectious TB if that individual has subsequently been determined not to have infectious TB.

Physician or Other Licensed Health Care Professional means an individual whose legally permitted scope of practice (i.e., license, registration, or certification) allows her or him to independently perform or be delegated to perform some or all of the health care services required by paragraph (g) of this section. Paragraph (g) requires that all medical evaluations and procedures and medical management and follow-up be performed by or under the supervision of a physician or other licensed health care professional, as appropriate. OSHA is aware that a variety of health care professionals are licensed by their respective states to legally perform different medical provisions required under this proposed standard. This definition clarifies that it is not OSHA's intent to dictate the specific type of health care professional to perform the activities required by the medical surveillance paragraph. OSHA's intent is merely that these activities be performed by persons who are legally permitted to independently perform or be delegated to perform some or all of the health care services required under the medical surveillance provisions of the standard. Employers wishing to use the services of a variety of health care providers must be familiar with the licensing laws of their state to ensure that the activities being performed are within the scope of that health care provider's licensure.

Powered air-purifying respirator (PAPR) means an air-purifying respirator that uses a blower to deliver air through the air-purifying element to the wearer's breathing zone. A PAPR uses a blower to draw ambient air through a filter and provide this filtered air, under pressure, to the facepiece of the wearer.

Qualitative fit test means a pass/fail fit test to assess the adequacy of respirator fit that relies on the respirator wearer's response. Generally, this assessment of adequacy of respirator fit is made by determining whether an individual wearing the respirator can detect the odor, taste, or irritation of a challenge agent introduced into the vicinity of the wearer's breathing zone.

Quantitative fit test means an assessment of the adequacy of respirator fit by numerically measuring the amount of leakage into the respirator. Leakage can be assessed through means such as measuring the concentration of a challenge agent (or air pressure) outside of the respirator versus the concentration of the agent (or air pressure) inside the respirator. The ratio of the two measurements is an index of the leakage of the seal between the respirator facepiece and the wearer's face.

Research laboratory is defined as a laboratory that propagates and manipulates cultures of *M. tuberculosis* in large volumes or high concentrations that are in excess of those used for identification and typing activities common to clinical laboratories. The purpose of this definition is to distinguish research laboratories from clinical laboratories. Under paragraph (e) of the proposed standard, research laboratories are required to meet additional provisions beyond those required for clinical laboratories (e.g., use of a hazard warning sign incorporating the biohazard symbol when materials containing *M. tuberculosis* are present in the laboratory and use of two sets of self-closing doors for entry into the work area from access corridors). These additional requirements are proposed due to the higher degree of hazard that may be present in research laboratories as a result of the presence of research materials that may contain *M. tuberculosis* in larger volumes and higher concentrations than would normally be found in diagnostic specimens or cultures in clinical laboratories.

Respirator means a device worn by an individual and intended to provide the wearer with respiratory protection against inhalation of airborne contaminants. While the term ''respirator'' may be used in medical situations to refer to a device that provides breathing assistance to an individual who is experiencing breathing difficulty, this section utilizes this term only in reference to the type of protective device defined above.

Suspected infectious tuberculosis means a potential disease state in which an individual is known, or with reasonable diligence should be known, by the employer to have one or more of the following conditions, unless the individual's condition has been medically determined to result from a cause other than TB: (1) to be infected with *M. tuberculosis* and to have the signs or symptoms of TB; (2) to have a positive acid-fast bacilli (AFB) smear; or (3) to have a persistent cough lasting 3 or more weeks and two or more symptoms of active TB (e.g., bloody sputum, night sweats, weight loss, fever, anorexia). An individual with suspected infectious TB has neither confirmed infectious TB nor has he or she been medically determined to be noninfectious.

Suspected infectious TB is another key term in the proposed standard. The presence of a person with suspected infectious TB triggers and is associated with a number of the provisions required of employers. Applying the criteria associated with suspected infectious TB is the first step in the early identification of individuals with infectious TB and is therefore a key factor in the elimination and minimization of occupational transmission of TB. Therefore, for purposes of implementing the standard it is important that what constitutes ''suspected infectious TB'' is clear.

The first criterion in identifying an individual as having suspected infectious TB is the presence of TB infection and the signs and symptoms of active TB. Under the second criterion, an individual would be suspected of having infectious TB if that individual had a positive AFB smear. The third criterion is based primarily on observation of an individual. The CDC states that:

> * * * A diagnosis of TB may be considered for any patient who has a persistent cough (i.e., a cough lasting for ≥ 3 weeks) or other signs or symptoms compatible with active TB (e.g., bloody sputum, night sweats, weight loss, anorexia

or fever). * * * Diagnostic measures for identifying TB should be conducted for patients in whom active TB is being considered. These measures include obtaining a medical history and performing a physical examination, PPD skin test, chest radiograph, and microscopic examination and culture of sputum or other appropriate specimens. (Ex. 4B)

OSHA has relied on the CDC's list of symptoms, but does not agree that employers need only ''consider'' a TB diagnosis when any of the symptoms appear. The Agency believes that requiring employers merely to consider a TB diagnosis under these circumstances may allow too many individuals with infectious TB to slip through this screen and remain unidentified. In addition, the CDC recommendations do not identify the minimum number of signs or symptoms that should trigger employer concern. The problem with the CDC's approach is that the signs and symptoms are so general that they would be difficult to apply in many of the occupational exposure circumstances covered by the standard. For example, if OSHA required employers to identify each individual with even one of the signs or symptoms of TB as having suspected infectious TB, too many individuals would be likely to be identified, thereby wasting valuable health care resources. For these reasons, OSHA has proposed that employers be required to determine that an individual has suspected infectious TB when the individual has a prolonged cough and at least two of the other signs or symptoms of infectious TB. The Agency believes that requiring the employer to identify individuals as suspect cases when they have only a prolonged cough, which is the primary mode of transmission, and at least 2 other signs or symptoms strikes the appropriate balance between over inclusion and under inclusion, i.e., between considering almost every individual in poor health as a suspect case and missing individuals who should be suspected of having infectious TB. OSHA believes that setting forth these more definitive criteria will meet the needs of the many employers covered by this standard who will not have skilled medical persons making initial determinations about whether or not an individual has suspected infectious TB. Employer who are in a position to make medical determinations are permitted by the standard to rule out infectious TB by determining that a given individual's signs and symptoms are the result of a cause other than TB.

That an employer knows or with reasonable diligence should know that an individual meets one or more of these criteria means that an employer must utilize the means at his or her disposal to gather relevant information about the individual. For example, the employer may have access to the medical records of the individual or may question an individual who has signs or symptoms of TB in order to obtain information about the individual, such as skin test status, AFB smear status, and so forth. How much questioning the employer might do depends on the work setting. For example, a hospital will have intake procedures that include asking questions, as will most homeless shelters and other fixed work sites. In other work settings, such as the many places in which emergency medical services and home health care are provided to unidentified individuals with infectious TB, the employer's obligation will be to respond when an employee notices signs or symptoms compatible with TB. In many of these instances, it is the training employees receive in identifying individuals with suspected TB that will be the most important factor.

In addition, as noted above, an individual who meets one or more of the above criteria but whose condition has been medically determined to result from a cause other than TB need not be considered to have suspected infectious TB. For example, a physician or other licensed health care professional, as appropriate, could determine that the signs and symptoms exhibited by the individual were the result, for example, of pneumonia and not TB.

Tight-fitting respirator means a respiratory inlet covering that is designed to form a complete seal with the face. A half-facepiece covers the nose and mouth while a full facepiece covers the nose, mouth, and eyes.

Tuberculosis (TB) means a disease caused by *M. tuberculosis*.

Tuberculosis infection means a condition in which living *M. tuberculosis* bacilli are present in the body, without producing clinically active disease. Although the infected individual has a positive tuberculin skin test reaction, the individual may have no symptoms related to the infection and may not be capable of transmitting the disease.

Tuberculosis disease is a condition in which living *M. tuberculosis* bacilli are present in the body, producing clinical illness. The individual may or may not be infectious.

Tuberculin skin test means a method used to evaluate the likelihood that a person is infected with *M. tuberculosis*. The method utilizes an intradermal injection of tuberculin antigen with subsequent measurement of reaction induration. It is also referred to as a PPD skin test.

Two-step testing is a baseline skin testing procedure used to differentiate between a boosted skin test reaction and a skin test reaction that signifies a new infection. If the initial skin test is negative, a second skin test is administered 1 to 3 weeks later. If the second skin test is positive, the reaction is probably due to boosting. If the second skin test is negative, the individual is considered to be not infected. A subsequent positive skin test in this individual would thus indicate a new infection. Boosting is discussed in more detail in connection with the Medical Surveillance paragraph.

Paragraph (k) Dates

As proposed, the final rule would become effective ninety (90) days after publication in the **Federal Register**. This will allow time for public distribution and give employers time to familiarize themselves with the standard. The various provisions have phased-in effective dates.

The employer's initial duty under the standard is the exposure determination and establishment of the written Exposure Control Plan required by paragraph (c) of this section. The plan would need to be completed 30 days after the effective date.

Thirty days later, 60 days after the effective date, paragraphs (h)(3), Information and Training, (g) Medical Surveillance, and (i) Recordkeeping would take effect.

Ninety (90) days after the effective date, the work practice procedures and engineering controls required by paragraph (d) (in work settings other than those noted below), the respiratory protection required by paragraph (f), and the labels and signs required by paragraphs (h) (1) and (2) would take effect. The work practices that are directly related to the engineering controls would have to be implemented as soon as the engineering controls were functional. Finally, the requirements for clinical and research laboratories contained in paragraph (e) would also take effect 90 days after the effective date.

For businesses with fewer than 20 employees, the engineering controls required by paragraph (d) of this section would take effect 270 days after the effective date. As noted above, the work practices directly related to the engineering controls being installed in accordance with paragraph (d) of this section must be implemented as soon as the engineering controls are

implemented. Since engineering controls may necessitate more extensive planning than is required to comply with other provisions of the standard, OSHA is proposing an extended phase-in for the smallest employers.

Since many employers have many of these provisions already in effect through current infection control plans, OSHA believes that these dates provide adequate time for compliance. Nevertheless, OSHA seeks comment on the appropriateness of the dates for compliance with the various provisions of the standard.

XI. Public Participation—Notice of Hearing

Interested persons are invited to submit written data, views, and arguments with respect to this proposed standard. These comments must be postmarked on or before December 16, 1997, and submitted in quadruplicate to the Docket Officer, Docket No. H–371, Room N2625, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210. Comments limited to 10 pages or less also may be transmitted by facsimile to (202) 219–5046, provided the original and three copies are sent to the Docket Officer thereafter.

Written submissions must clearly identify the provisions of the proposal that are being addressed and the position taken with respect to each issue. The data, views, and arguments that are submitted will be available for public inspection and copying at the above address. All timely written submissions will be made a part of the record of the proceeding.

Pursuant to section 6(b)(3) of the Act, an opportunity to submit oral testimony concerning the issues raised by the proposed standard will be provided at an informal public hearing scheduled to begin at 10:00 A.M. on February 3, 1998, in Washington, DC in the Auditorium of the Frances Perkins Building, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210.

Notice of Intention to Appear

All persons desiring to participate at the hearings must file in quadruplicate a notice of intention to appear postmarked on or before December 16, 1997 addressed to the Docket Officer, Docket No. H–371, Room N–2625, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210; telephone (202) 219–7894. The Notice of Intention to Appear also may be transmitted by facsimile to (202) 219–5046, provided the original and 3 copies of the notice are sent to the above address thereafter.

The Notices of Intention to Appear, which will be available for inspection and copying at the OSHA Docket Office, must contain the following information:

(1) The name, address, and telephone number of each person to appear;

(2) The hearing site that the party is requesting to attend;

(3) The capacity in which the person will appear;

(4) The approximate amount of time requested for the presentation;

(5) The specific issues that will be addressed;

(6) A detailed statement of the position that will be taken with respect to each issue addressed;

(7) Whether the party intends to submit documentary evidence, and if so, a brief summary of that evidence; and

(8) Whether the party wishes to testify on the days set aside to focus on homeless shelters.

Filing of Testimony and Evidence Before Hearings

Any party requesting more than 10 minutes for a presentation at the hearing, or who will submit documentary evidence, must provide in quadruplicate the complete text of the testimony, including any documentary evidence to be presented at the hearing to the Docket Officer at the above address. This material must be postmarked by December 31, 1997 and will be available for inspection and copying at the OSHA Docket Office. Each such submission will be reviewed in light of the amount of time requested in the Notice of Intention to Appear. In those instances where the information contained in the submission does not justify the amount of time requested, a more appropriate amount of time will be allocated and the participant will be notified of that fact.

Any party who has not substantially complied with this requirement may be limited to a 10-minute presentation. Any party who has not filed a Notice of Intention to Appear may be allowed to testify, as time permits, at the discretion of the Administrative Law Judge.

OSHA emphasizes that the hearing is open to the public, and that interested persons are welcome to attend. However, only persons who have filed proper notices of intention to appear will be entitled to ask questions and otherwise participate fully in the proceeding.

Conduct and Nature of Hearings

The hearings will commence at 10:00 a.m. on February 3, 1998. At that time any procedural matters relating to the proceeding will be resolved.

The nature of an informal hearing is established in the legislative history of section 6 of the Act and is reflected by the OSHA hearing regulations (see 29 CFR 1911.15 (a)). Although the presiding officer is an Administrative Law Judge and questioning by interested persons is allowed on crucial issues, the proceeding shall remain informal and legislative in type. The essential intent is to provide an opportunity for effective oral presentations that can proceed expeditiously in the absence of rigid procedures that would impede or protract the rulemaking process.

Additionally, since the hearing is primarily for information gathering and clarification, it is an informal administrative proceeding, rather than an adjudicative one. The technical rules of evidence, for example, do not apply. The regulations that govern hearings and the pre-hearing guidelines to be issued for this hearing will ensure fairness and due process and also facilitate the development of a clear, accurate and complete record. Those rules and guidelines will be interpreted in a manner that furthers that development. Thus, questions of relevance, procedure and participation generally will be decided so as to favor development of the record.

The hearing will be conducted in accordance with 29 CFR Part 1911. The hearing will be presided over by an Administrative Law Judge who makes no recommendation on the merits of OSHA's proposal. The responsibility of the Administrative Law Judge is to ensure that the hearing proceeds at a reasonable pace and in an orderly manner. The Administrative Law Judge, therefore, will have all the powers necessary and appropriate to conduct a full and fair informal hearing as provided in 29 CFR Part 1911 and the prehearing guidelines, including the powers:

(1) To regulate the course of the proceedings;

(2) To dispose of procedural requests, objections, and comparable matters;

(3) To confine the presentation to the matters pertinent to the issues raised;

(4) To regulate the conduct of those present at the hearing by appropriate means;

(5) At the Judge's discretion, to question and permit the questioning of any witness and to limit the time for questioning; and

(6) At the Judges's discretion, to keep the record open for a reasonable, stated time to written information and additional data, views and arguments from any person who has participated in the oral proceeding.

Information on Homeless Shelter Issues for the Public Hearing

OSHA seeks to gather additional information related to homeless shelters during the written comment period and the public hearing. OSHA recognizes the unique service provided by homeless shelters, yet is also aware that shelters serve a client population that has been identified as possessing a high prevalence of active TB. OSHA is seeking information on all aspects of TB and employee protection against occupational transmission of TB in homeless shelters (e.g., means successfully being used by shelters to achieve early identification of shelter clients with suspected or confirmed infectious TB; successful programs currently being used to protect employees against occupational transmission of TB).

The Agency intends to designate a special session during the Washington, D.C. hearing to focus on the issues surrounding homeless shelters. We encourage hearing participants whose primary testimony will involve homeless shelters to indicate this in their Notice of Intention to Appear; OSHA will attempt to schedule these participants on the day(s) of the hearing set aside to focus on homeless shelters. Other participants whose testimony will not be primarily on homeless shelter issues but who wish to address the topic of homeless shelters will be scheduled another day, but they may enter a separate statement in the record during this period. In any case, participants are free to discuss homeless shelters or any other issue related to this proposed standard whenever they present their testimony.

Certification of Record and Final Determination After Hearing

Following the close of the posthearing comment period, the presiding Administrative Law Judge will certify the record to the Assistant Secretary of Labor for Occupational Safety and Health. The Administrative Law Judge does not make or recommend any decisions as to the content of the final standard.

The proposed standard will be reviewed in light of all testimony and written submissions received as part of the record, and a standard will be issued based on the entire record of the proceeding, including the written comments and data received from the public.

List of Subjects

29 CFR Part 1910

Health professionals, Occupational safety and health, Reporting and recordkeeping requirements, Tuberculosis.

XII. Authority and Signature

This document was prepared under the direction of Greg Watchman, Acting Assistant Secretary of Labor, 200 Constitution Avenue, N.W., Washington, D.C., 20210.

It is issued under sections 4, 6, and 8 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657), Secretary of Labor's Order 1–90 (55 FR 9033) and 29 CFR Part 1911.

Signed at Washington, DC, this 15th day of September, 1997.

Greg Watchman,

Acting Assistant Secretary of Labor.

XIII. The Proposed Standard

General Industry

Part 1910 of Title 29 of the Code of Federal Regulations is proposed to be amended as follows:

PART 1910—[AMENDED]

Subpart Z—[Amended]

1. The general authority citation for Subpart Z of 29 CFR Part 1910 continues to read as follows and a new citation for § 1910.1035 is added:

Authority: Secs. 6 and 8, Occupational Safety and Health Act, 29 U.S.C. 655, 657, Secretary of Labor's Orders Nos. 12–71 (36 FR 8754), 8–76 (41 FR 25059), or 9–83 (48 FR 35736), as applicable; and 29 CFR Part 1911.

* * * * *

Section 1910.1035 also issued under 29 U.S.C. 653.

* * * * *

2. Section 1910.1035 is added to read as follows:

§ 1910.1035 Tuberculosis

(a) Scope. This section applies to occupational exposure to tuberculosis (TB) occurring:

(1) In hospitals;

(2) In long term care facilities for the elderly;

(3) In correctional facilities and other facilities that house inmates or detainees;

(4) In hospices;

(5) In shelters for the homeless;

(6) In facilities that offer treatment for drug abuse;

(7) In facilities where high-hazard procedures (as defined by this section) are performed;

(8) In laboratories that handle specimens that may contain *M. tuberculosis,* or process or maintain the resulting cultures, or perform related activity that may result in the aerosolization of *M. tuberculosis;*

Note to paragraph (a)(8): Occupational exposure incurred in any of the work settings listed in paragraphs (a)(1) through (a)(8) of this section by temporary or contract employees or by personnel who service or repair air systems or equipment or who renovate, repair, or maintain areas of buildings that may reasonably be anticipated to contain aerosolized *M. tuberculosis* is covered by this section.

(9) During the provision of social work, social welfare services, teaching, law enforcement or legal services if the services are provided in any of the work settings listed in paragraphs (a)(1) through (a)(8) of this section, or in residences, to individuals who are in AFB isolation or are segregated or otherwise confined due to having suspected or confirmed infectious TB.

(10) During the provision of emergency medical services, home health care and home-based hospice care.

(b) Application. An employer covered under paragraph (a) of this section, Scope (other than the operator of a laboratory), may choose to comply only with the provisions of appendix A to this section if the Exposure Control Plan demonstrates that his or her facility or work setting: (1) Does not admit or provide medical services to individuals with suspected or confirmed infectious TB; and

(2) Has had no case of confirmed infectious TB in the past 12 months; and

(3) Is located in a county that, in the past 2 years, has had 0 cases of confirmed infectious TB reported in one year and fewer than 6 cases of confirmed infectious TB reported in the other year.

(c) Exposure control—(1) *Exposure determination.* (i) Each employer who has any employee with occupational exposure shall prepare an exposure determination that contains the following:

(A) A list of the job classifications in which all employees have occupational exposure; *and*

(B) A list of the job classifications in which some employees have occupational exposure, and a list of all tasks and procedures (or groups of closely related tasks and procedures) that these employees perform and that involve occupational exposure.

(ii) The exposure determination shall be made without regard to the use of respiratory protection.

(2) *Exposure Control Plan.* (i) Each employer who has any employee with occupational exposure shall establish a written Exposure Control Plan that must include:

(A) The exposure determination required by paragraph (c)(1) of this section;

(B) Procedures for providing information about individuals with suspected or confirmed infectious TB or about air that may reasonably be anticipated to contain aerosolized *M. tuberculosis* to occupationally exposed employees who need this information in order to take proper precautions; and

(C) Procedures for reporting an exposure incident, including procedures specifying the individual to whom the incident is to be reported, and procedures for evaluating the circumstances surrounding the exposure incident.

(ii) Each employer who transfers individuals with suspected or confirmed infectious TB to a facility with AFB isolation capabilities shall include in the Exposure Control Plan procedures for prompt identification, masking or segregation, and transfer of such individuals.

Note to paragraph (c)(2)(ii): An employer's duties regarding transfer will vary with the type of facility the employer operates and the work performed by his or her employees. For example, the transfer responsibilities of hospitals, long-term care facilities for the elderly, correctional facilities, and hospices may include contacting the receiving facility, providing transport, and taking other steps to ensure that the individual with suspected or confirmed infectious TB reaches the receiving facility. By contrast, the responsibilities of facilities that do not maintain custody over individuals, such as homeless shelters or facilities that offer treatment for drug abuse, might only include providing information about the receiving facility, contacting the facility, and providing directions to the facility.

(iii) Each employer in whose facility individuals with suspected or confirmed infectious TB are admitted or provided medical services shall include each of the following provisions in the Exposure Control Plan:

(A) Procedures for prompt identification of individuals with suspected or confirmed infectious TB;

(B) Procedures for isolating and managing the care of individuals with suspected or confirmed infectious TB, including:

(*1*) Minimizing the time an individual with suspected or confirmed infectious TB remains outside of an AFB isolation room or area (e.g., in an emergency room);

(*2*) Minimizing employee exposure in AFB isolation rooms or areas by combining tasks to limit the number of entries into the room or area and by minimizing the number of employees who must enter and minimizing the time they spend in the room or area;

(*3*) Delaying elective transport or relocation within the facility of an individual with suspected or confirmed infectious TB. Procedures are to be established to assure that, to the extent feasible, services and procedures for individuals with suspected or confirmed infectious TB are brought into or conducted in an AFB isolation room or area;

(*4*) Using properly-fitted masks (e.g., surgical masks, valveless respirators) on individuals with suspected or confirmed infectious TB or transporting such individuals in portable containment engineering controls when relocation or transport outside of AFB isolation rooms or areas is unavoidable. Procedures are to be established to assure that the individual is returned to an AFB isolation room or area as soon as is practical after completion of the service or procedure;

(*5*) Delaying elective high-hazard procedures or surgery until an individual with suspected or confirmed infectious TB is determined to be noninfectious;

(C) A list of all high-hazard procedures, if any, performed in the work setting; and

(D) A schedule for inspection, maintenance, and performance monitoring of engineering controls (see appendix E to this section).

(iv) Each employer who operates a laboratory shall include in the Exposure Control Plan a determination from the director of the laboratory as to whether the facility should operate at Biosafety Level 2 or 3 containment according to current CDC recommendations (CDC/NIH Biosafety in Microbiological and Biomedical Laboratories). The laboratory director shall determine and document the need for:

(A) Controlled access;

(B) Anterooms;

(C) Sealed windows;

(D) Directional airflow;

(E) Measures to prevent recirculation of laboratory exhaust air;

(F) Filtration of exhaust air before discharge outside; and

(G) Thimble exhaust connections for biological safety cabinets.

(v) Each employer who provides home health care or home-based hospice care shall include in the Exposure Control Plan procedures for prompt identification of individuals with suspected or confirmed infectious TB and procedures for minimizing employee exposure to such individuals; a list of the high-hazard procedures, if any, performed in the work setting; and procedures for delaying elective high-hazard procedures or surgery until the individual is noninfectious.

(vi) Each employer who claims reduced responsibilities related to paragraph (b), Application, or paragraph (g)(3)(iii)(D), Medical Surveillance, of this section shall document in the Exposure Control Plan the number of individuals with confirmed infectious tuberculosis encountered in the work setting in the past 12 months.

(vii) The Exposure Control Plan shall be:

(A) Accessible to employees in accordance with 29 CFR 1910.20(e);

(B) Reviewed at least annually and updated whenever necessary to reflect new or modified tasks, procedures, or engineering controls that affect occupational exposure and to reflect new or revised employee job classifications with occupational exposure; and

(C) Made available for examination and copying to the Assistant Secretary and/or the Director upon request.

(d) Work Practices and Engineering Controls. (1) Work practices and engineering controls shall be used to eliminate or minimize employee exposures to *M. tuberculosis.*

(2) The work practices in the Exposure Control Plan shall be implemented.

(3) Individuals with suspected or confirmed infectious TB shall be identified, and except in settings where home health care or home-based hospice care is being provided, shall be:

(i) Masked or segregated in such a manner that contact with employees who are not wearing respiratory protection is eliminated or minimized until transfer or placement in an AFB isolation room or area can be accomplished; and

(ii) Placed in an AFB isolation room or area or transferred to a facility with AFB isolation rooms or areas within 5 hours from the time of identification, or temporarily placed in AFB isolation within 5 hours until placement or transfer can be accomplished as soon as possible thereafter.

(4) High-hazard procedures shall be conducted in an AFB isolation room or area.

(5) Engineering controls shall be used in facilities that admit or provide medical services or AFB isolation to individuals with suspected or confirmed infectious TB except in

settings where home health care or home-based hospice care is being provided.

(i) Negative pressure shall be maintained in AFB isolation rooms or areas.

(ii) Negative pressure shall be qualitatively demonstrated (e.g., by smoke trails) daily while a room or area is in use for TB isolation (see appendix G to this section).

(iii) Engineering controls shall be maintained, and inspected and performance monitored for filter loading and leakage every 6 months, whenever filters are changed, and more often if necessary to maintain effectiveness (see appendix E to this section).

(iv) Air from AFB isolation rooms or areas shall be exhausted directly outside, away from intake vents, employees, and the general public. Air that cannot be exhausted in such a manner or must be recirculated must pass through HEPA filters before discharge or recirculation.

(v) Ducts carrying air that may reasonably be anticipated to contain aerosolized *M. tuberculosis* shall be maintained under negative pressure for their entire length before in-duct HEPA filtration or until the ducts exit the building for discharge.

(vi) Doors and windows of AFB isolation rooms or areas shall be kept closed while in use for TB isolation, except when doors are opened for entering or exiting and when windows are part of the ventilation system being used to achieve negative pressure.

(vii) When an AFB isolation room or area is vacated by an individual with suspected or confirmed infectious TB, the room or area shall be ventilated according to current CDC recommendations for a removal efficiency of 99.9% before permitting employees to enter without respiratory protection (see appendix C to this section).

(6) The employer shall provide information about the TB hazard to any contractor who provides temporary or contract employees who may incur occupational exposure so that the contractor can institute precautions to protect his or her employees.

(e) Clinical and Research Laboratories. (1) This paragraph applies to clinical and research laboratories that engage in the culture, production, concentration, experimentation, or manipulation of *M. tuberculosis.* The requirements in this paragraph apply in addition to the other requirements of the standard.

(2) Clinical and research laboratories shall meet the following criteria:

(i) Standard microbiological practices.

(A) Procedures shall be performed in a manner that minimizes the creation of aerosols.

(B) Mouth pipetting shall be prohibited.

(C) Work surfaces and laboratory equipment shall be decontaminated at the end of each shift and after any spill of viable material.

(D) Cultures, stocks and other wastes contaminated with *M. tuberculosis* shall be decontaminated before disposal by a decontamination method, such as autoclaving, known to effectively destroy *M. tuberculosis.* Materials to be decontaminated outside of the immediate laboratory shall be placed in a durable, leakproof container, closed and sealed for transport from the laboratory and labeled or color-coded in accordance with paragraph (h)(1)(ii) of this section.

(ii) *Special practices.* (A) Access to the laboratory shall be limited by the laboratory director when work with *M. tuberculosis* is in progress.

(B) A biosafety manual that includes procedures for spill management shall be adopted. The employer shall review the manual as necessary and at least annually. The employer shall update the biosafety manual as necessary to reflect changes in the work setting. Employees shall be advised of potential hazards, shall be required to read instructions on practices and procedures, and shall be required to follow them.

(C) Cultures, tissues, or specimens of body fluids contaminated with *M. tuberculosis* shall be placed in a container that prevents leakage during collection, handling, processing, storage, transport, or shipping.

(D) All spills shall be immediately contained and cleaned up by employees who are properly trained and equipped to work with potentially concentrated *M. tuberculosis.* A spill or accident that results in an exposure incident shall be reported immediately to the laboratory director or other designated person.

(E) When materials containing or animals infected with *M. tuberculosis* are present in the laboratory or containment module, a hazard warning sign, in accordance with paragraph (h)(2)(iv), incorporating the universal biohazard symbol, shall be posted on all laboratory and animal room access doors.

(iii) *Containment equipment.* (A) Certified biological safety cabinets (Class 2) shall be used whenever procedures with a potential for generating aerosols of *M. tuberculosis* are conducted or whenever high concentrations or large volumes of *M. tuberculosis* are used. Such materials may be centrifuged in the open laboratory if sealed rotor heads or centrifuge safety cups are used, and if these rotors or safety cups are opened in a biological safety cabinet.

(B) Biological safety cabinets shall be certified when installed, annually thereafter, whenever they are moved, and whenever filters are changed.

(iv) Laboratory facilities. A method for decontamination of wastes contaminated with *M. tuberculosis* (e.g., autoclave, chemical disinfection, incinerator, or other decontamination system known to effectively destroy *M. tuberculosis*) shall be available within or as near as feasible to the work area.

(3) Research laboratories shall meet the following additional criteria:

(i) *Special practices.* (A) Laboratory doors shall be kept closed when work involving *M. tuberculosis* is in progress.

(B) Access to the work area shall be limited to authorized persons. Written policies and procedures shall be established so that only persons who have been advised of the potential biohazard, who meet any specific entry requirements, and who comply with all entry and exit procedures shall be allowed to enter the work areas and animal rooms.

(C) Respiratory protection shall be worn when aerosols cannot be safely contained (e.g., when aerosols are generated outside of a biological safety cabinet).

(ii) *Containment equipment.* Certified biological safety cabinets (Class 2 or 3) or appropriate combinations of personal protection or physical containment devices, such as respirators, centrifuge safety cups, sealed centrifuge rotors, and containment caging for animals, shall be used for manipulations of cultures and those clinical or environmental materials that may be a source of aerosols containing *M. tuberculosis;* aerosol challenge of animals with *M. tuberculosis;* harvesting of tissues or fluids from animals infected with *M. tuberculosis;* or the necropsy of animals infected with *M. tuberculosis.*

(iii) *Laboratory facilities.* (A) The laboratory shall be separated from areas that are open to unrestricted traffic flow within the building. Passage through two sets of self-closing doors shall be required for entry into the work area from access corridors or other contiguous areas.

(B) Windows in the laboratory shall be closed and sealed.

(C) A ducted exhaust air ventilation system shall be provided. This system shall create directional airflow that draws air from ''clean'' areas into the laboratory toward ''contaminated'' areas. The employer shall verify the proper direction of the airflow (i.e., into

the work area) at least every six months. The exhaust air shall not be recirculated to any other area of the building, shall be discharged to the outside, and shall be dispersed away from occupied areas and air intakes.

(D) The high efficiency particulate air (HEPA)-filtered exhaust air from Class 2 or Class 3 biological safety cabinets shall be discharged directly to the outside or through the building exhaust system. If the HEPA-filtered exhaust air from Class 2 or 3 biological safety cabinets is to be discharged to the outside through the building exhaust air system, it shall be connected to this system in a manner (e.g., thimble units) that avoids any interference with the air balance of the cabinets or building exhaust system.

(E) Continuous flow centrifuges or other equipment that may produce aerosols shall be contained in devices that exhaust air through HEPA filters before discharge into the laboratory.

(f) Respiratory Protection—(1) *General.* (i) Each employer shall provide a respirator to each employee who:

(A) Enters an AFB isolation room or area in use for TB isolation;

(B) Is present during the performance of procedures or services for an individual with suspected or confirmed infectious TB who is not masked;

(C) Transports an individual with suspected or confirmed infectious TB in an enclosed vehicle (e.g., ambulance, helicopter) or who transports an individual with suspected or confirmed infectious TB within the facility when that individual is not masked;

(D) Repairs, replaces, or maintains air systems or equipment that may reasonably be anticipated to contain aerosolized *M. tuberculosis;*

(E) Is working in an area where an unmasked individual with suspected or confirmed infectious TB has been segregated or otherwise confined (e.g., while awaiting transfer); or

(F) Is working in a residence where an individual with suspected or confirmed infectious TB is known to be present.

(ii) Each employer who operates a research laboratory shall provide a respirator to each employee who is present when aerosols of *M. tuberculosis* cannot be safely contained (e.g., when aerosols are generated outside of a biological safety cabinet).

(iii) The employer shall provide the respirator at no cost to the employee and shall assure that the employee uses the respirator in accordance with the requirements of this section.

(iv) The employer shall assure that the employee dons the respirator before entering any of the work settings or performing any of the tasks set forth in paragraphs (f)(1)(i) and (f)(1)(ii) of this section and uses it until leaving the work setting or completing the task, regardless of other control measures in place.

(2) *Respiratory Protection Program.* (i) Each employer who has any employee whose occupational exposure is based on entering any of the work settings or performing any of the tasks described in paragraph (f)(1) of this section shall establish and implement a written respiratory protection program that assures respirators are properly selected, fitted, used, and maintained. The program shall include the following elements:

(A) Procedures for selecting the appropriate respirators for use in the work setting;

(B) A determination of each employee's ability to wear a respirator, as required under paragraph (g)(3)(ii) of this section, Medical Surveillance, for each employee required to wear a respirator;

(C) Procedures for the proper use of respirators;

(D) Fit testing procedures for tight-fitting respirators;

(E) Procedures and schedules for cleaning, disinfecting, storing, inspecting, repairing, or otherwise maintaining respirators;

(F) Training of employees to assure the proper use and maintenance of the respirator, as required under paragraph (h) of this section, Communication of Hazards and Training; and

(G) Procedures for periodically evaluating the effectiveness of the program.

(ii) The employer shall designate a person qualified by appropriate training or experience to be responsible for the administration of the respiratory protection program and for conducting the periodic evaluations of its effectiveness.

(iii) The employer shall review and update the written program as necessary to reflect current workplace conditions and respirator use.

(iv) The employer shall, upon request, make the written respiratory protection program available to affected employees, their designated representatives, the Assistant Secretary, and the Director. A copy of the program shall be submitted to the Assistant Secretary and/or the Director, if requested.

(3) *Respirator Selection.* (i) The employer shall select and provide properly fitted negative pressure or more protective respirators. Negative pressure respirators shall be capable of being:

(A) Qualitatively or quantitatively fit tested in a reliable way to verify a face-seal leakage of no more than 10%; and

(B) Fit checked by the employee each time the respirator is donned.

(ii) The employer shall select a respirator that will function effectively in the conditions of the work setting. In addition to meeting the criteria in paragraph (f)(3)(i) of this section, the respirator shall be, at a minimum, either a HEPA respirator selected from among those jointly approved as acceptable by the Mine Safety and Health Administration and by the National Institute for Occupational Safety and Health (NIOSH) under the provisions of 30 CFR part 11, or an N95 respirator certified by NIOSH under the provisions of 42 CFR part 84.

(4) *Respirator Use.* (i) The employer shall not permit any respirator that depends on a tight face-to-facepiece seal for effectiveness to be worn by employees having any condition that prevents such a seal. Examples of these conditions include, but are not limited to, facial hair that comes between the sealing surface of the facepiece and the face or if facial hair interferes with valve function, absence of normally worn dentures, facial scars, or headgear that projects under the facepiece seal.

(ii) The employer shall assure that each employee who wears corrective glasses or goggles wears them in a manner that does not interfere with the seal of the facepiece to the face of the wearer.

(iii) Disposable respirators shall be discarded when excessive resistance, physical damage, or any other condition renders the respirator unsuitable for use.

(iv) The employer shall assure that each employee, upon donning a tight-fitting respirator, performs a facepiece fit check prior to entering a work area where respirators are required. The procedures in appendix B to this section or other procedures recommended by the respirator manufacturer that provide protection equivalent to that provided by the procedures in appendix B shall be used.

(v) Respirators shall be immediately repaired, or discarded and replaced, when they are no longer in proper working condition.

(vi) The employer shall permit each employee to leave the respirator use area as soon as practical to:

(A) Change the filter elements or replace the respirator whenever the ability of the respirator to function effectively is compromised or the employee detects a change in breathing resistance; or

(B) Wash his or her face and respirator facepiece as necessary to prevent skin irritation associated with respirator use.

(vii) Each employee required to wear a respirator under this section shall be evaluated in accordance with paragraph (g), Medical Surveillance, of this section.

(viii) No employee shall be assigned a task requiring the use of a respirator if, based upon the employee's most recent evaluation, the physician or other licensed health care professional, as appropriate, determines that the employee will be unable to function adequately while wearing a respirator. If the physician or other licensed health care professional, as appropriate, determines that the employee's job activities must be limited, or that the employee must be removed from the employee's current job because of the employee's inability to wear a respirator, the limitation or removal shall be performed in accordance with paragraph (g)(5)(iii) of this section.

(5) *Fit Testing.* (i) The employer shall perform either quantitative or qualitative face fit tests in accordance with the procedures outlined in appendix B to this section.

(ii) The employer shall assure that each employee who must wear a tight-fitting respirator passes a fit test:

(A) At the time of initial fitting;

(B) Whenever changes occur in the employee's facial characteristics which affect the fit of the respirator;

(C) Whenever a different size or make of respirator is used; and

(D) At least annually thereafter unless the annual determination required under paragraph (g)(3)(ii)(A), Medical Surveillance, of this section indicates that the annual fit test is not necessary.

(iii) When quantitative fit testing is performed, the employer shall not permit an employee to wear a tight-fitting half-mask respirator unless a minimum fit factor of one hundred (100) is obtained in the test chamber.

(6) *Maintenance and care of reusable and powered air purifying respirators.* (i) Respirators shall be cleaned and disinfected using the cleaning procedures recommended by the manufacturer at the following intervals:

(A) As necessary for respirators issued for the exclusive use of an employee; and

(B) After each use for respirators issued to more than one employee.

(ii) Respirators shall be inspected before each use and during cleaning after each use;

(iii) Respirator inspections shall include:

(A) A check of respirator function, tightness of connections and the condition of the facepiece, head straps, valves, connecting tube, and cartridges, canisters, or filters; and

(B) A check of the rubber or elastomer parts for pliability and signs of deterioration.

(iv) Respirators that fail to pass inspection shall be removed from service and shall be repaired or adjusted in accordance with the following:

(A) Repairs or adjustments to respirators are only to be made with NIOSH-approved parts designed for the respirator by the respirator manufacturer, and conducted by persons appropriately trained to perform such operations;

(B) Only repairs of the type and extent covered by the manufacturer's recommendations may be performed; and

(C) Reducing or admission valves or regulators shall be returned to the manufacturer or given to an appropriately trained technician for adjustment or repair.

(v) Respirators shall be stored in a manner that protects them from contamination, damage, dust, sunlight, extreme temperatures, excessive moisture, and damaging chemicals and prevents deformation of the facepiece or exhalation valve.

(7) *Identification of filters, cartridges, and canisters.* (i) Filters, cartridges, and canisters used in the workplace shall be properly labeled and color-coded with the NIOSH approval label as required by 30 CFR part 11 or 42 CFR part 84, whichever is applicable, before they are placed into service.

(ii) The NIOSH approval label on a filter, cartridge, or canister shall not be intentionally removed, obscured, or defaced while it is in service in the workplace.

(8) *Respiratory protection program evaluation.* The employer shall review the overall respiratory protection program at least annually, and shall conduct inspections of the workplace as necessary to assure that the provisions of the program are being properly implemented for all affected employees. The review of the program shall include an assessment of each element required under paragraph (f)(2) of this section.

(g) Medical Surveillance—(1) *General.* (i) Each employer who has any employee with occupational exposure shall provide the employee with medical surveillance as described in this paragraph.

(ii) Each employer covered under paragraph (a), *Scope,* of this section shall provide information about the signs and symptoms of pulmonary TB, a medical history, a physical examination, TB skin testing, medical management and follow-up and, if indicated, other related tests and procedures, and medical removal protection if the employee develops infectious TB, to any of his or her employees who have an exposure incident while working in a covered work setting, even if such employee is not categorized as having occupational exposure.

(iii) Medical surveillance provisions, including examinations, evaluations, determinations, procedures, and medical management and follow-up, shall be:

(A) Provided at no cost to the employee;

(B) Provided at a reasonable time and place for the employee;

(C) Performed by or under the supervision of a physician or other licensed health care professional, as appropriate; and

(D) Provided according to recommendations of CDC current at the time these evaluations and procedures take place, except as specified by this paragraph (g).

(iv) Laboratory tests shall be conducted by an accredited laboratory.

(2) *Explanation of Terms.* This paragraph explains the terms used in paragraph (g).

(i) *Medical history* emphasizes the pulmonary system, and includes previous exposure to *M. tuberculosis,* BCG vaccination, TB skin test results, TB disease, prior and current preventive or therapeutic treatment, current signs or symptoms of active TB disease, and factors affecting immunocompetence;

(ii) *Physical examination* emphasizes the pulmonary system, signs and symptoms of active TB disease, and factors affecting immunocompetence;

(iii) *TB skin testing,* includes anergy testing if indicated, and is only for employees whose TB skin test status is not known to be positive. An initial 2-step protocol is to be used for each employee who has not been previously skin tested and/or for whom a negative test cannot be documented within the past 12 months. If the employer has documentation that the employee has had a negative TB skin test within the past 12 months, that test may be utilized to fulfill the skin testing portion of this requirement. Periodic retesting shall be performed in accordance with paragraph (g)(3) of this section.

(iv) ''Determination of the employee's ability to wear a respirator'' is a face-to-face assessment of the health factors affecting respirator use and the need for the annual fit test.

Note to paragraph (g)(2)(iv): A determination of the need for the annual fit

test may only be performed after the required initial fit test of the employee and cannot be used in lieu of any other required fit tests, for example, when a different size or make of respirator is used.

(v) ''Medical management and follow-up'' include diagnosis, and, where appropriate, prophylaxis and treatment related to TB infection and disease.

(vi) *Other related tests and procedures* include those associated with TB infection and disease and determined to be necessary by the physician or other licensed health care professional, as appropriate.

(vii) Medical Removal Protection is the maintenance of earnings, seniority and other benefits specified in paragraph (g)(5) of this section for an employee who has confirmed or suspected infectious TB or is unable to wear a respirator.

(3) *Application*. (i) Each employee with occupational exposure shall be provided with the following at the times specified:

(A) Before initial assignment to a job with occupational exposure or within 60 days of the effective date of this standard and at least annually thereafter: A medical history and TB skin testing, and, if indicated, a physical examination and other related tests and procedures;

Note to paragraph (g)(3)(i)(A): If an employee has had a medical examination within the twelve (12) months preceding the effective date of the standard and the employer has the documented results of that examination, only the medical surveillance provisions required by the standard that were not included in the examination need to be provided. The date(s) of the previous medical examination and skin test shall be used to determine the date(s) of the employee's next medical examination and skin test but in no case shall the interval between the previous examination and skin test and the next examination and skin test exceed 12 months.

(B) When the employee has signs or symptoms of TB, either observed or self-reported: A medical history, a physical examination, TB skin testing, medical management and follow-up, and, if indicated, other related tests and procedures;

(C) When an employee undergoes an exposure incident: A medical history, TB skin testing as soon as feasible (unless there is documented negative TB skin testing within the past 3 months), and if the result is negative, another skin test 3 months later, medical management and follow-up and, if indicated, a physical examination and other related tests and procedures;

(D) When the employee has a TB skin test conversion: A medical history, a physical examination, medical management and follow-up, and, if indicated, other related tests;

(E) Within 30 days of the termination of employment: A TB skin test; and

(F) At any other time the physician or other licensed health care professional, as appropriate, deems it necessary: Any or all the provisions of paragraph (g).

(ii) Each employee who must wear a respirator shall be provided with the following at the times specified:

(A) Before initial assignment to a job with occupational exposure or within 60 days of the effective date of this standard and at least annually thereafter: A determination of the employee's ability to wear a respirator; and

(B) When the wearer experiences unusual difficulty while being fitted or while using a respirator: A determination of the employee's ability to wear a respirator, including relevant components of a medical history, and, if indicated, a physical examination and other related tests and procedures.

(iii) An employee with negative TB skin test status shall be provided with a TB skin test every 6 months if the employee in the course of his or her duties:

(A) Enters an AFB isolation room or area;

(B) Performs or is present during the performance of high-hazard procedures;

(C) Transports or is present during the transport of an individual with suspected or confirmed infectious TB in an enclosed vehicle; or

(D) Works in an intake area where early identification procedures are performed (e.g., emergency departments, admitting areas) in facilities where six (6) or more individuals with confirmed infectious TB have been encountered in the past twelve months.

(4) *Additional Requirements.* (i) The employer shall assure that when the physician or other licensed health care professional, as appropriate, determines that an employee has suspected or confirmed infectious TB, the physician or other licensed health care professional, as appropriate, shall notify the employer and the employee as soon as feasible.

(ii) When the employer first identifies an individual with confirmed infectious TB, the employer shall notify each employee who has had an exposure incident involving that individual of his or her exposure to confirmed TB; and

(iii) When an exposure incident results in a TB skin test conversion, the employer shall assure that a determination is made of the drug susceptibility of the *M. tuberculosis* isolate from the source, unless the employer can demonstrate that such a determination is not feasible.

(iv) When an exposure incident or a TB skin test conversion occurs, the employer shall investigate and document the circumstances surrounding the exposure incident or conversion (e.g. failure of engineering controls or work practices and events leading to the exposure incident) to determine if changes can be instituted to prevent similar occurrences in the future.

(5) *Medical Removal Protection.* (i) Each employee with suspected or confirmed infectious TB shall be removed from the workplace until determined to be noninfectious.

(ii) For each employee who is removed from the workplace under paragraph (g)(5)(i) of this section, the employer shall maintain the total normal earnings, seniority, and all other employee rights and benefits, including the employee's right to his or her former job status, as if the employee had not been removed from the employee's job or otherwise medically limited until the employee is determined to be noninfectious or for a maximum of 18 months, whichever comes first.

(iii) For each employee who is removed from his or her job under paragraph (f)(4)(viii), Respiratory Protection, of this section the employer shall transfer the employee to comparable work for which the employee is qualified or can be trained in a short period (up to 6 months), where the use of respiratory protection is not required. The employer shall maintain the total normal earnings, seniority, and all other employee rights and benefits. If there is no such work available, the employer shall maintain the employee's total normal earnings, seniority, and all other employee rights and benefits until such work becomes available or for a maximum of 18 months, whichever comes first.

(iv) An employer's obligation to provide earnings, seniority and other benefits to a removed employee may be reduced to the extent that the employee receives compensation for earnings lost during the period of removal either from a publicly or employer-funded compensation program or from employment with another employer made possible by virtue of the employee's removal.

(6) *Information Provided to Physician or Other Licensed Health Care Professionals.* (i) Each employer shall assure that all physicians or other licensed health care professionals responsible for making determinations and performing procedures as part of the medical surveillance program are

provided a copy of this regulation and, for those employees required to wear respirators under this section, information regarding the type of respiratory protection used, a description of the work effort required, any special environmental conditions (e.g., heat, confined space entry), additional requirements for protective clothing and equipment, and the duration and frequency of usage of the respirator.

(ii) Each employer shall assure that the physician or other licensed health care professional, as appropriate, who evaluates an employee after an exposure incident is provided the following information:

(A) A description of the exposed employee's duties as they relate to the exposure incident;

(B) Circumstances under which the exposure incident occurred;

(C) Any diagnostic test results, including drug susceptibility pattern or other information relating to the source of exposure which could assist in the medical management of the employee; and

(D) All of the employee's medical records relevant to the management of the employee, including tuberculin skin testing results.

(7) *Written Opinion.* (i) Each employer shall obtain and provide the employee with a copy of the written opinion of the physician or other licensed health care professional, as appropriate, within 15 days of the completion of all medical evaluations required by this section.

(ii) The written opinion shall be limited to the following information:

(A) The employee's TB skin test status;

(B) The employee's infectivity status;

(C) A statement that the employee has been informed of the results of the medical evaluation;

(D) A statement that the employee has been told about any medical conditions resulting from exposure to TB that require further evaluation or treatment;

(E) Recommendations for medical removal or work restrictions and the physician's or other licensed health care professional's opinion regarding the employee's ability to wear a respirator.

(iii) All other findings or diagnoses shall remain confidential and shall not be included in the written report.

(h) Communication of Hazards and Training—(1) *Labels.* (i) Air systems that may reasonably be anticipated to contain aerosolized *M. tuberculosis* shall be labeled ''Contaminated Air—Respiratory Protection Required.'' The label shall be placed at all points where ducts are accessed prior to a HEPA filter and at duct access points, fans, and discharge outlets of non-HEPA filtered direct discharge systems.

(ii) Clinical and research laboratory wastes that are contaminated with *M. tuberculosis* and are to be decontaminated outside of the immediate laboratory shall be labeled with the biohazard symbol or placed in a red container(s).

(2) *Signs.* (i) Signs shall be posted at the entrances to:

(A) Rooms or areas used to isolate an individual with suspected or confirmed infectious TB;

(B) Areas where procedures or services are being performed on an individual with suspected or confirmed infectious TB; and

(C) Clinical and research laboratories where *M. tuberculosis* is present.

(ii) When an AFB isolation room or area is vacated by an individual with suspected or confirmed infectious TB, unless the individual has been medically determined to be noninfectious, the sign shall remain posted at the entrance until the room or area has been ventilated according to CDC recommendations for a removal efficiency of 99.9% (see Appendix C to this section).

(iii) Signs for AFB isolation rooms or areas, except as required in paragraph (h)(2)(iv) of this section, shall be readily observable and shall bear the following legend with symbol and text in white on a red background:

BILLING CODE 4510–26–P

BILLING CODE 4510–26–C

No Admittance Without Wearing a Type N95 or More Protective Respirator

Note to paragraph (h)(2)(ii): Employers may include additional information on signs provided it does not interfere with conveyance of this message.

(iv) Signs at the entrances of clinical or research laboratories and autopsy suites where procedures are being performed that may generate aerosolized *M. tuberculosis* shall include the biohazard symbol, name and telephone number of the laboratory director or other designated responsible person, the infectious agent designation *Mycobacterium tuberculosis*, and special requirements for entering the laboratory or autopsy room.

(3) *Information and Training.* (i) Each employer shall assure that each employee with occupational exposure participates in a training program, which must be provided at no cost to the employee and be made available at a reasonable time and place.

(ii) Training shall be provided as follows:

(A) Before initial assignment to tasks where occupational exposure may occur;

(B) Within 60 days after the effective date of the standard; and

(C) At least annually thereafter, unless the employer can demonstrate that the employee has the specific knowledge and skills required under paragraph (h)(3)(vii) of this section. The employer must provide re-training to the employee in any topic(s) in which specific knowledge and skills cannot be demonstrated.

Note to paragraph (h)(3)(ii): Training in the general topics under paragraph (h)(3)(vii) of this section which has been provided in the past 12 months by a previous employer may be transferred to an employee's new employer. However, the new employer must provide training in the site-specific topics under paragraph (h)(3)(vii) in accordance with the requirements of paragraph (h).

(iii) For employees who have received training on TB in the year preceding the effective date of the standard, only training with respect to the provisions of the standard that were not included in such training need be provided. The annual retraining shall be conducted within one year from the date of the training that occurred before the effective date of the standard.

(iv) Annual training for each employee shall be provided within one calendar year of the employee's previous training.

(v) The employer shall provide additional training when changes such as modification of tasks or procedures or institution of new tasks or procedures affect the employee's occupational exposure. The additional training may be limited to addressing the new or modified exposures.

(vi) Material appropriate in content and vocabulary to the educational level, literacy, and language of employees shall be used.

(vii) The training program shall include an explanation of:

(A) The contents of this standard and the location of an accessible copy of the regulatory text of this standard;

(B) The general epidemiology of TB, including Multidrug-Resistant TB (MDR–TB), and the potential for exposure within the facility; the signs and symptoms of TB, including the difference between tuberculosis

infection and tuberculosis disease; the modes of transmission of tuberculosis, including the possibility of reinfection in persons with a positive tuberculin skin test; and the personal health conditions that increase the employee's risk of developing TB disease if infected (e.g., HIV infection, prolonged corticosteroid therapy, other immunocompromising conditions);

(C) The employer's exposure control plan and respiratory protection program and the means by which the employee can review the written plans;

(D) The tasks and other activities that may involve exposure to *M. tuberculosis*;

(E) The use and limitations of methods that will prevent or reduce exposure, including appropriate engineering controls, work practices, respiratory protection, and site-specific control measures;

(F) Why a respirator is necessary, and the basis of selection of the respirators used, the types of respirators used, upkeep and storage of the respirators used, and their location and proper use, including procedures for inspection, donning and removal, checking the fit and seals, and wearing the respirator. This instruction shall allow sufficient practice to enable the employee to become thoroughly familiar with and effective in performing these tasks;

(G) The employer's medical surveillance program, including the purpose of tuberculin skin testing, the importance of a positive or negative skin test result, anergy testing, and the importance of participation in the program;

(H) The procedures to follow if an exposure incident occurs, including the method of reporting the incident and the medical management and follow-up that the employer is required to provide, and the benefits and risks of prophylaxis; and

(I) The procedures to follow if the employee develops signs or symptoms of TB disease.

(viii) The person(s) conducting the training shall be knowledgeable in the subject matter covered by the elements contained in the training program as it relates to the workplace that the training will address.

(ix) The employer shall provide employees with an opportunity for interactive questions and answers with the person conducting the training session.

(i) Recordkeeping—(1) *Medical Records.* (i) Each employer shall establish and maintain an accurate record for each employee with occupational exposure, in accordance with 29 CFR 1910.1020.

(ii) This record shall include:

(A) The name, social security number, and job classification of the employee;

(B) A copy of all results of examinations; medical testing, including the employee's tuberculin skin test status; and follow-up procedures;

(C) The employer's copy of the physician's or other licensed health care professional's written opinion; and

(D) A copy of the information provided to the physician or other licensed health care professional.

(iii) Confidentiality. The employer shall assure that employee medical records required by paragraph (i) are:

(A) Kept confidential; and

(B) Not disclosed or reported without the employee's express written consent to any person within or outside the workplace, except as required by this section or as may be required by law.

(iv) The employer shall maintain the records required by paragraph (i)(1) for at least the duration of employment plus 30 years, in accordance with 29 CFR 1910.1020. The medical records of employees who have worked for less than one year for the employer need not be retained beyond the term of employment if they are provided to the employee upon termination of employment.

(2) *OSHA Illness and Injury Records.* The employer shall record TB infection or disease in accordance with 29 CFR 1904 and 29 CFR 1960, as applicable.

(3) *Training Records.* (i) Training records shall include the following information:

(A) The dates of the training sessions;

(B) The contents or a summary of the training sessions;

(C) The names and qualifications of persons conducting the training; and

(D) The name and job classification of all persons attending the training sessions.

(ii) Training records shall be maintained for 3 years from the date on which the training occurred.

(4) *Engineering Control Maintenance and Monitoring Records.* (i) Engineering control maintenance records shall include the following information:

(A) Date;

(B) Equipment identification;

(C) Task performed; and

(D) Sign-off.

(ii) Performance monitoring records shall include the following information:

(A) Date and time;

(B) Location;

(C) Parameter measured, including units when appropriate;

(D) Results of monitoring; and

(E) Sign-off.

(iii) Engineering control maintenance and monitoring records shall be maintained for three years.

(5) *Availability.* (i) Employee medical records required by paragraph (i)(1), Recordkeeping, of this section shall be provided upon request for the examination and copying to the subject employee, to anyone having the written consent of the subject employee, to the Director, and to the Assistant Secretary in accordance with 29 CFR 1910.1020. OSHA Illness and Injury Records shall be accessible under the provisions of 29 CFR 1904 and 29 CFR 1960, as applicable.

(ii) Employee training records required by paragraph (i)(3), Recordkeeping, of this section shall be provided upon request for examination and copying to employees, to their representatives, to the Director, and to the Assistant Secretary.

(iii) Engineering control maintenance and monitoring records required by paragraph (i)(4), Recordkeeping, of this section shall be provided upon request for examination and copying to employees, their representatives, to the Director, and to the Assistant Secretary.

(6) *Transfer of Records.* (i) The employer shall comply with the requirements involving transfer of records set forth in 29 CFR 1910.1020(h) and 29 CFR 1904 and 29 CFR 1960, as applicable.

(ii) If the employer ceases to do business and there is no successor employer to receive and retain the records for the prescribed period, the employer shall notify the Director at least three months before their disposal and transmit them to the Director, if required by the Director to do so, within the three month period.

(j) *Definitions.* For the purposes of this section, the following shall apply:

Acid-fast bacilli (AFB) means bacteria that retain certain dyes after being washed in an acid solution. Most acid-fast organisms are mycobacteria.

Accredited laboratory means a laboratory that has participated in a quality assurance program leading to a certification of competence administered by a governmental or private organization that tests and certifies laboratories.

Air-purifying respirator means a respirator that is designed to remove air contaminants from the ambient air or air surrounding the respirator.

AFB isolation room or area includes, but is not limited to, rooms, areas, booths, tents, or other enclosures that are maintained at negative pressure to adjacent areas in order to control the spread of aerosolized *M. tuberculosis.*

Anergy means the inability of a person to react to skin test antigens (even if the person is infected with the organisms tested) because of immunosuppression.

Assistant Secretary means the Assistant Secretary of Labor for Occupational Safety and Health, or designated representative.

BCG (Bacille Calmette-Guerin) vaccine is a tuberculosis vaccine.

Canister or *cartridge* means a container with a filter, sorbent, or catalyst, or a combination of these items, that removes specific air contaminants from the air drawn through the container.

Clinical laboratory is a laboratory or area of a facility that conducts routine and repetitive operations for the diagnosis of TB such as preparing acid-fast smears and culturing sputa or other clinical specimens for identification, typing or susceptibility testing.

Confirmed infectious tuberculosis is a disease state that has been diagnosed by positive identification of *M. tuberculosis* from body fluid or tissue through positive culture, positive gene probe, or positive polymerase chain reaction (PCR). The disease state must be capable of being transmitted to another individual (e.g., pulmonary or laryngeal TB or extrapulmonary TB where the infected tissue is exposed and could generate droplet nuclei).

Conversion means a change in tuberculin skin test results from negative to positive, based upon current Centers for Disease Control and Prevention (CDC) guidelines.

Director means the Director of the National Institute for Occupational Safety and Health, U.S. Department of Health and Human Services, or designated representative.

Disposable respirator means a respiratory protective device that cannot be resupplied with an unused filter or cartridge and that is to be discarded in its entirety after its useful service life has been reached.

Exposure incident means an event in which an employee has been exposed to an individual with confirmed infectious TB or to air containing aerosolized *M. tuberculosis* without the benefit of applicable exposure control measures required by this section.

Filter means a component used in respirators to remove solid or liquid aerosols from the inspired air.

Fit factor means a quantitative measure of the fit of a particular respirator on a particular individual.

High efficiency particulate air (HEPA) filter means a specialized filter that is capable of removing 99.97% of particles greater than or equal to 0.3 micrometer in diameter.

High hazard procedures are procedures performed on an individual with suspected or confirmed infectious tuberculosis in which the potential for being exposed to *M. tuberculosis* is increased due to the reasonably anticipated generation of aerosolized *M. tuberculosis.* Such procedures include, but are not limited to, sputum induction, bronchoscopy, endotracheal intubation or suctioning, aerosolized administration of pentamidine or other medications, and pulmonary function testing. They also include autopsy, clinical, surgical and laboratory procedures that may aerosolize *M. tuberculosis.*

M. tuberculosis means *Mycobacterium tuberculosis,* the scientific name of the bacillus that causes tuberculosis.

Negative pressure means the relative air pressure difference between two areas. A room that is under negative pressure has lower pressure than adjacent areas, which keeps air from flowing out of the room and into adjacent rooms or areas.

Negative pressure respirator means a respirator in which the air pressure inside the facepiece is negative during inhalation with respect to the ambient air pressure outside the respirator.

Occupational exposure means reasonably anticipated contact, that results from the performance of an employee's duties, with an individual with suspected or confirmed infectious TB or air that may contain aerosolized *M. tuberculosis.*

Physician or other licensed health care professional means an individual whose legally permitted scope of practice (i.e., license, registration, or certification) allows him or her to independently provide or be delegated the responsibility to provide some or all of the health care services required by paragraph (g) of this section.

Powered air-purifying respirator (PAPR) means an air-purifying respirator that uses a blower to deliver air through the air-purifying element to the wearer's breathing zone.

Qualitative fit test means a pass/fail fit test to assess the adequacy of respirator fit that relies on the respirator wearer's response to a challenge agent.

Quantitative fit test means an assessment of the adequacy of respirator fit by numerically measuring the amount of leakage into the respirator.

Research laboratory is a laboratory that propagates and manipulates cultures of *M. tuberculosis* in large volumes or high concentrations that are in excess of those used for identification and typing activities common to clinical laboratories.

Respirator means a device worn by an individual and intended to provide the wearer with respiratory protection against inhalation of airborne contaminants.

Suspected infectious tuberculosis means a potential disease state in which an individual is known, or with reasonable diligence should be known, by the employer to have one or more of the following conditions, unless the individual's condition has been medically determined to result from a cause other than TB:

(1) To be infected with *M. tuberculosis* and to have the signs or symptoms of TB;

(2) To have a positive acid-fast bacilli (AFB) smear; or

(3) To have a persistent cough lasting 3 or more weeks and two or more symptoms of active TB (e.g., bloody sputum, night sweats, weight loss, fever, anorexia). An individual with suspected infectious TB has neither confirmed infectious TB nor has he or she been medically determined to be noninfectious.

Tight-fitting facepiece means a respiratory inlet covering that is designed to form a complete seal with the face. A half-facepiece covers the nose and mouth; a full facepiece covers the nose, mouth, and eyes.

Tuberculosis (TB) means a disease caused by *M. tuberculosis.*

Tuberculosis infection means a condition in which living *M. tuberculosis* bacilli are present in the body without producing clinically active disease. Although the infected individual has a positive tuberculin skin test reaction, he or she may have no symptoms related to the infection and may not be capable of transmitting the disease.

Tuberculosis disease is a condition in which living *M. tuberculosis* bacilli are present in the body, producing clinical illness. The individual may or may not be infectious.

Tuberculin skin test means a method used to evaluate the likelihood that a person is infected with *M. tuberculosis.* The method utilizes an intradermal injection of tuberculin antigen with subsequent measurement of the reaction induration. It is also referred to as a PPD skin test.

Two-step testing is a baseline skin testing procedure used to identify a boosted skin test reaction from that of a new infection. The procedure involves placing a second skin test 1 to 3 weeks after an initial negative test. A positive reaction on the second test indicates a boosted reaction.

(k) Dates.—(1) *Effective Date.* The standard shall become effective on [insert date 90 days after publication of final rule in the **Federal Register**].

(2) *Start-up dates.* (i) *Exposure control.* The exposure control provisions required by paragraph (c) of this section shall take effect on [insert date 30 days after effective date of final rule].

(ii) The *Information and Training* provisions required under paragraph (h)(3), the *Medical surveillance* provisions required by paragraph (g), and the *Recordkeeping* provisions required by paragraph (i) of this section shall take effect on [insert date 60 days after effective date of final rule].

(iii) *Work practices and Engineering controls.* The work practice and engineering control provisions required by paragraph (d) of this section shall take effect on [insert date 90 days after effective date of final rule]. For businesses with fewer than 20 employees, engineering controls required by paragraph (d) of this section shall take effect [insert 270 days after effective date of final rule]. Work practice controls that are directly related to engineering controls being installed in accordance with this paragraph shall be implemented as soon as those engineering controls are implemented.

(iv) *Respiratory protection.* Respiratory protection provisions required by paragraph (f) of this section shall take effect on [insert date 90 days after effective date of final rule].

(v) *Labels and signs.* The labels and signs provisions required by paragraphs (h)(1) and (h)(2) of this section shall take effect on [insert date 90 days after effective date of final rule].

(vi) *Clinical and research laboratories.* The additional requirements for Clinical and Research Laboratories contained in paragraphs (e)(1) through (e)(3) shall take effect on [insert date 90 days after effective date of final rule].

Appendix A to § 1910.1035—Provisions for Employers Claiming Reduced Responsibilities Under Paragraph (b), Application (Mandatory)

(c) Exposure Control

Paragraph (c)(1)(i & ii) Exposure Determination
(c)(2)(i) Written Exposure Control Plan with the following elements:
(c)(2)(i)(A) The exposure determination
(c)(2)(i)(B) Procedures for providing information to employees about individuals identified with suspected or confirmed infectious TB or air that may reasonably be anticipated to contain aerosolized M. tuberculosis
(c)(2)(i)(C) Procedures for reporting an exposure incident
(c)(2)(ii) Procedures for identifying, masking or segregating and transferring individuals with suspected or confirmed infectious TB
(c)(2)(vi) Documentation of the number of individuals with confirmed infectious TB encountered in the past 12 months
(c)(2)(vii) (A–C) Accessible exposure control plan, reviewed annually and updated as necessary, and made available to the Assistant Secretary and Director

(d) Work Practice Procedures and Engineering Controls

(d)(1) Use of work practices to eliminate or minimize employee exposure
(d)(2) Implementation of the work practice procedures in the exposure control plan
(d)(3)(i) Identification and masking or segregating of individuals with suspected or confirmed infectious TB
(d)(3)(ii) Temporary isolation of individuals who cannot be transferred within 5 hours
(d)(5)(i–vii) Engineering controls if temporary isolation is used
(d)(6) Provide information about TB hazards to temporary or personnel who may incur occupational exposure

(g) Medical Surveillance

(g)(1)(i–iv) Medical surveillance program for each employee with occupational exposure or who has an exposure incident in one of the covered work settings, at no cost, at a reasonable time, by a physician or other licensed health care professional, according to current recommendations of the CDC and with laboratory tests conducted by an accredited laboratory
(g)(2)(i, ii, iii, v, vi & vii) Explanation of terms: Medical history, Physical examination, tuberculin skin testing, medical management and follow-up, medical removal protection, and other related tests and procedures
(g)(3)(i)(A) Initial TB skin testing and medical history (NOTE: Annual skin testing and medical histories are not required)
(g)(3)(i)(B) Medical history, TB skin testing and follow-up for employees who develop signs or symptoms of TB
(g)(3)(i)(C) Medical history, TB skin testing and medical management and follow-up of employees after an exposure incident
(g)(4)(i) Notification of employee and employer as soon as feasible about infectious TB disease status of the employee
(g)(4)(ii) Notification of employees about previously unidentified individuals with infectious TB
(g)(4)(iii) Determination of drug susceptibility of *M. tuberculosis* source after an exposure incident
(g)(4)(iv) Investigations of exposure incidents and TB skin test conversions
(g)(5)(i, ii & iv) Medical removal and protection of benefits for individuals with infectious TB
(g)(6)(i & ii) Information provided to the physician or other licensed health care professional
(g)(7)(i–iii) Physician or other licensed health care professional's written opinion

(h) Communication of Hazards and Training

(h)(1)(i) If temporary isolation is used, label air systems that may reasonably be anticipated to contain aerosolized *M. tuberculosis*
(h)(2)(i)(A) If temporary isolation is used, post signs at entrance to temporary isolation
(h)(2)(ii) When temporary isolation room or area is vacated by an individual with suspected or confirmed infectious TB, ventilate for an appropriate period
(h)(2)(iii) Signs for temporary isolation rooms or areas must have a stop sign with the legend ''No Admittance Without Wearing a Type N95 or More Protective Respirator''
(h)(3)(i–viii) Annual training with specified elements for employees with occupational exposure

(i) Recordkeeping

(i)(1)(i–iv) Medical Records
(i)(2) OSHA Illness and Injury Records
(i)(3)(i & ii) Training Records
(i)(4)(i–iii) If temporary isolation is used, engineering control maintenance records
(i)(5)(i & ii) Availability of medical and training records
(i)(6)(i & ii) Transfer of records

(k) Dates

(k)(1) Effective date
(k)(2)(i, ii & iii) Start up dates for exposure control, medical surveillance, information and training, recordkeeping, and work practices and engineering controls

Appendix B to § 1910.1035—Fit Testing Procedures (Mandatory)

Part I. Approved Fit Test Protocols

A. Fit Testing Procedures

The employer shall conduct fit testing using the following procedures. These provisions apply to both QLFT and QNFT.

1. The test subject shall be allowed to pick the most acceptable respirator from a selection of respirators of various sizes and models.

2. Prior to the selection process, the test subject shall be shown how to put on a respirator, how it should be positioned on the face, how to set strap tension and how to determine an acceptable fit. A mirror shall be available to assist the subject in evaluating the fit and positioning the respirator. This instruction may not constitute the subject's formal training on respirator use, as it is only a review.

3. The test subject shall be informed that he or she is being asked to select the respirator that provides the most acceptable fit. Each respirator represents a different size and shape, and if fitted and used properly, will provide adequate protection.

4. The test subject shall be instructed to hold each chosen facepiece up to the face and eliminate those that obviously do not give an acceptable fit.

5. The more acceptable facepieces are noted; the most acceptable mask is donned

and worn at least five minutes to assess acceptability. Assistance in assessing acceptability can be given by discussing the points in item 6 below. If the test subject is not familiar with using a particular respirator, the test subject shall be directed to don the mask several times and to adjust the straps each time to become adept at setting proper tension on the straps.

6. Assessment of acceptability shall include reviewing the following points with the test subject and allowing the test subject adequate time to determine the acceptability of the respirator:

(a) Position of the mask on the nose,

(b) Room for eye protection,

(c) Room to talk;

(d) Position of mask on face and cheeks.

7. The following criteria shall be used to help determine the adequacy of the respirator fit:

(a) Chin properly placed;

(b) Adequate strap tension, not overly tightened;

(c) Fit across nose bridge;

(d) Respirator of proper size to span distance from nose to chin;

(e) Tendency of respirator to slip;

(f) Self-observation in mirror to evaluate fit and respirator position.

8. The test subject shall conduct the negative and positive pressure fit checks as described in this appendix or other fit check procedures recommended by the respirator manufacturer providing equivalent protection to the procedures in this appendix. Before conducting the negative or positive pressure fit checks, the subject shall be told to seat the mask on the face by moving the head from side-to-side and up and down slowly while taking in a few slow deep breaths. Another facepiece shall be selected and retested if the test subject fails the fit check tests.

9. The test shall not be conducted if there is any hair growth between the skin and the facepiece sealing surface, such as stubble beard growth, beard, mustache or sideburns that cross the respirator sealing surface. Any type of apparel which interferes with a satisfactory fit shall be altered or removed.

10. If a test subject exhibits difficulty in breathing during the tests, she or he shall be referred to a physician or other licensed health care professional, as appropriate, to determine whether the test subject can wear a respirator while performing her or his duties.

11. If the employee finds the fit of the respirator unacceptable, the test subject shall be given the opportunity to select a different respirator and to be retested.

12. *Exercise regimen.* Prior to the commencement of the fit test, the test subject shall be given a description of the fit test and the test subject's responsibilities during the test procedure. The description of the process shall include a description of the test exercises that the subject will be performing. The respirator to be tested shall be worn for at least 5 minutes before the start of the fit test.

13. *Test Exercises.* The test subject shall perform exercises, in the test environment, while wearing any applicable safety equipment that may be worn during actual respirator use which could interfere with fit, in the manner described below:

(a) *Normal breathing.* In a normal standing position, without talking, the subject shall breathe normally.

(b) *Deep breathing.* In a normal standing position, the subject shall breathe slowly and deeply, taking caution so as to not hyperventilate.

(c) *Turning head side to side.* Standing in place, the subject shall slowly turn his or her head from side to side between the extreme positions on each side. The head shall be held at each extreme momentarily so the subject can inhale at each side.

(d) *Moving head up and down.* Standing in place, the subject shall slowly move his/her head up and down. The subject shall be instructed to inhale in the up position (i.e., when looking toward the ceiling).

(e) *Talking.* The subject shall talk out loud slowly and loud enough so as to be heard clearly by the test conductor. The subject can read from a prepared text such as the Rainbow Passage, count backward from 100, or recite a memorized poem or song.

Rainbow Passage

When the sunlight strikes raindrops in the air, they act like a prism and form a rainbow. The rainbow is a division of white light into many beautiful colors. These take the shape of a long round arch, with its path high above, and its two ends apparently beyond the horizon. There is, according to legend, a boiling pot of gold at one end. People look, but no one ever finds it. When a man looks for something beyond reach, his friends say he is looking for the pot of gold at the end of the rainbow.

(f) *Grimace.* The test subject shall grimace by smiling or frowning. (Only for QNFT testing, not performed for QLFT)

(g) *Bending over.* The test subject shall bend at the waist as if he/she were to touch his/her toes. Jogging in place shall be substituted for this exercise in those test environments such as shroud type QNFT units which prohibit bending at the waist.

(h) *Normal breathing.* Same as exercise (a).

Each test exercise shall be performed for one minute except for the grimace exercise which shall be performed for 15 seconds.

The test subject shall be questioned by the test conductor regarding the acceptability of the respirator upon completion of the protocol. If it has become unacceptable, another model of respirator shall be tried.

B. Qualitative Fit Test (QLFT) Protocols

1. General

(a) The employer shall assign specific individuals who shall assume full responsibility for implementing the respirator qualitative fit test program.

(b) The employer shall ensure that persons administering QLFT are able to prepare test solutions, calibrate equipment and perform tests properly, recognize invalid tests, and assure that test equipment is in proper working order.

(c) The employer shall assure that QLFT equipment is kept clean and well maintained so as to operate within the parameters for which it was designed.

2. Isoamyl Acetate Protocol

Note: This protocol is not appropriate, by itself, for fit testing particulate respirators. If chosen for use in fit testing particulate respirators, the respirator must be equipped with an organic vapor cartridge, provided the employee will be using the same facepiece in the work setting except that it will be equipped with particulate filters.

(a) Odor threshold screening. The odor threshold screening test, performed without wearing a respirator, is intended to determine if the individual tested can detect the odor of isoamyl acetate.

(1) Three 1 liter glass jars with metal lids are required.

(2) Odor free water (e.g. distilled or spring water) at approximately 25 degrees C shall be used for the solutions.

(3) The isoamyl acetate (IAA) (also known at isopentyl acetate) stock solution is prepared by adding 1 cc of pure IAA to 800 cc of odor free water in a 1 liter jar and shaking for 30 seconds. A new solution shall be prepared at least weekly.

(4) The screening test shall be conducted in a room separate from the room used for actual fit testing. The two rooms shall be well ventilated to prevent the odor of IAA from becoming evident in the general room air where testing takes place.

(5) The odor test solution is prepared in a second jar by placing 0.4 cc of the stock solution into 500 cc of odor free water using a clean dropper or pipette. The solution shall be shaken for 30 seconds and allowed to stand for two to three minutes so that the IAA concentration above the liquid may reach equilibrium. This solution shall be used for only one day.

(6) A test blank shall be prepared in a third jar by adding 500 cc of odor free water.

(7) The odor test and test blank jars shall be labeled 1 and 2 for jar identification. Labels shall be placed on the lids so they can be periodically peeled off and switched to maintain the integrity of the test.

(8) The following instruction shall be typed on a card and placed on the table in front of the two test jars (i.e., 1 and 2): The purpose of this test is to determine if you can smell banana oil at a low concentration. The two bottles in front of you contain water. One of these bottles also contains a small amount of banana oil. Be sure the covers are on tight, then shake each bottle for two seconds. Unscrew the lid of each bottle, one at a time, and sniff at the mouth of the bottle. Indicate to the test conductor which bottle contains banana oil.

(9) The mixtures used in the IAA odor detection test shall be prepared in an area separate from where the test is performed, in order to prevent olfactory fatigue in the subject.

(10) If the test subject is unable to correctly identify the jar containing the odor test solution, the IAA qualitative fit test shall not be performed.

(11) If the test subject correctly identifies the jar containing the odor test solution, the test subject may proceed to respirator selection and fit testing.

(b) *Isoamyl acetate fit test.* (1) The fit test chamber shall be similar to a clear 55-gallon drum liner suspended inverted over a 2-foot

diameter frame so that the top of the chamber is about 6 inches above the test subject's head. The inside top center of the chamber shall have a small hook attached.

(2) Each respirator used for the fitting and fit testing shall be equipped with organic vapor cartridges or offer protection against organic vapors.

(3) After selecting, donning, and properly adjusting a respirator, the test subject shall wear it to the fit testing room. This room shall be separate from the room used for odor threshold screening and respirator selection, and shall be well ventilated, as by an exhaust fan or lab hood, to prevent the test medium that is not contained will be removed from the general room air.

(4) A copy of the test exercises and any prepared text from which the subject is to read shall be taped to the inside of the test chamber.

(5) Upon entering the test chamber, the test subject shall be given a 6-inch by 5-inch piece of paper towel, or other porous, absorbent, single-ply material, folded in half and wetted with 0.75 cc of pure IAA. The test subject shall hang the wet towel on the hook at the top of the chamber.

(6) Allow two minutes for the IAA test concentration to stabilize before starting the fit test exercises. This would be an appropriate time to talk with the test subject; to explain the fit test, the importance of his/her cooperation, and the purpose for the test exercises; or to demonstrate some of the exercises.

(7) If at any time during the test, the subject detects the banana like odor of IAA, the test is failed. The subject shall quickly exit from the test chamber and leave the test area to avoid olfactory fatigue.

(8) If the test is failed, the subject shall return to the selection room and remove the respirator. The test subject shall repeat the odor sensitivity test, select and put on another respirator, return to the test area and again begin the fit test procedure described in (1) through (7) above. The process continues until a respirator that fits well has been found. Should the odor sensitivity test be failed, the subject shall wait about 5 minutes before retesting. Odor sensitivity will usually have returned by this time.

(9) When the subject wearing the respirator passes the test, its efficiency shall be demonstrated for the subject by having the subject break the face seal and take a breath before exiting the chamber.

(10) When the test subject leaves the chamber, the subject shall remove the saturated towel and return it to the person conducting the test, so there is no significant IAA concentration buildup in the chamber during subsequent tests. The used towels shall be kept in a self sealing bag to keep the test area from being contaminated.

3. Saccharin Solution Aerosol Protocol

The entire screening and testing procedure shall be explained to the test subject prior to the conduct of the screening test.

(a) Taste threshold screening. The saccharin taste threshold screening, performed without wearing a respirator, is intended to determine whether the individual being tested can detect the taste of saccharin.

(1) During threshold screening as well as during fit testing, subjects shall wear an enclosure about the head and shoulders that is approximately 12 inches in diameter by 14 inches tall with at least the front portion clear and that allows free movements of the head when a respirator is worn. An enclosure substantially similar to the 3M hood assembly, parts # FT 14 and # FT 15 combined, is adequate.

(2) The test enclosure shall have a ¾-inch hole in front of the test subject's nose and mouth area to accommodate the nebulizer nozzle.

(3) The test subject shall don the test enclosure. Throughout the threshold screening test, the test subject shall breathe through his/her slightly open mouth with tongue extended.

(4) Using a nebulizer device such as the DeVilbiss Model 40 Inhalation Medication Nebulizer or equivalent, the test conductor shall spray the *threshold check solution* into the enclosure. This nebulizer shall be clearly marked to distinguish it from the fit test solution nebulizer.

(5) The *threshold check solution* consists of 0.83 grams of sodium saccharin USP in 100 ml of warm water. It can be prepared by putting 1 ml of the fit test solution (see (b)(5) below) in 100 ml of distilled water.

(6) To produce the aerosol, the nebulizer bulb is firmly squeezed so that it collapses completely, and is then released and allowed to fully expand.

(7) Ten squeezes are repeated rapidly and then the test subject is asked whether the saccharin can be tasted.

(8) If the first response is negative, ten more squeezes are repeated rapidly and the test subject is again asked whether the saccharin is tasted.

(9) If the second response is negative, ten more squeezes are repeated rapidly and the test subject is again asked whether the saccharin is tasted.

(10) The test conductor will take note of the number of squeezes required to solicit a taste response.

(11) If the saccharin is not tasted after 30 squeezes (step 10), the test subject may not perform the saccharin fit test.

(12) If a taste response is elicited, the test subject shall be asked to take note of the taste for reference in the fit test.

(13) Correct use of the nebulizer means that approximately 1 ml of liquid is used at a time in the nebulizer body.

(14) The nebulizer shall be thoroughly rinsed in water, shaken dry, and refilled at least each morning and afternoon or at least every four hours.

(b) Saccharin solution aerosol fit test procedure.

(1) The test subject may not eat, drink (except plain water), smoke, or chew gum for 15 minutes before the test.

(2) The fit test uses the same enclosure described in (a) above.

(3) The test subject shall don the enclosure while wearing the respirator selected in section I.A. above. The respirator shall be properly adjusted and equipped with a particulate filter(s).

(4) A second nebulizer device such as the DeVilbiss Model 40 Inhalation Medication Nebulizer or equivalent is used to spray the fit test solution into the enclosure. This nebulizer shall be clearly marked to distinguish it from the screening test solution nebulizer.

(5) The fit test solution is prepared by adding 83 grams of sodium saccharin to 100 ml of warm water.

(6) As before, the test subject shall breathe through the slightly open mouth with tongue extended.

(7) The nebulizer is inserted into the hole in the front of the enclosure and the fit test solution is sprayed into the enclosure using the same number of squeezes required to elicit a taste response in the screening test. A minimum of 10 squeezes is required.

(8) After generating the aerosol the test subject shall be instructed to perform the exercises in section I. A. 13 above.

(9) Every 30 seconds the aerosol concentration shall be replenished using one half the number of squeezes as initially.

(10) The test subject shall indicate to the test conductor if at any time during the fit test the taste of saccharin is detected.

(11) If the taste of saccharin is detected, the fit is deemed unsatisfactory and a different respirator shall be tried.

4. Bitrex (Denatonium benzoate) Solution Aerosol Qualitative Fit Test Protocol

The Bitrex (Denatonium benzoate) solution aerosol QLFT protocol uses the published saccharin test protocol because of its current acceptance and past validation. Bitrex is routinely used as a taste aversion agent in household liquids which children should not be drinking and is endorsed by the American Medical Association, the National Safety Council, and the American Association of Poison Control Centers. The entire screening and testing procedure shall be explained to the test subject prior to the conduct of the screening test.

(a) Taste Threshold Screening. The Bitrex taste threshold screening, performed without wearing a respirator, is intended to determine whether the individual being tested can detect the taste of Bitrex.

(1) During threshold screening as well as during fit testing, subjects shall wear an enclosure about the head and shoulders that is approximately 12 inches (30.5 cm) in diameter by 14 inches (35.6 cm) tall. The front portion of the enclosure shall be clear from the respirator and allow free movement of the head when a respirator is worn. An enclosure substantially similar to the 3M hood assembly, parts # 14 and # 15 combined, is adequate.

(2) The test enclosure shall have a ¾ inch (1.9 cm) hole in front of the test subject's nose and mouth area to accommodate the nebulizer nozzle.

(3) The test subject shall don the test enclosure. Throughout the threshold screening test, the test subject shall breathe through his or her slightly open mouth with tongue extended.

(4) Using a nebulizer device such as a DeVilbiss Model 40 Inhalation Medication Nebulizer or equivalent, the test conductor shall spray the *threshold check solution* into the enclosure. This nebulizer shall be clearly marked to distinguish it from the fit test solution nebulizer.

(5) The *threshold check solution* consists of 13.5 milligrams of Bitrex in 100 ml of 5% NaCl solution in distilled water.

(6) To produce the aerosol, the nebulizer bulb is firmly squeezed so that the bulb collapses completely, and is then released and allowed to fully expand.

(7) Ten squeezes are repeated rapidly and then the test subject is asked whether the Bitrex can be tasted.

(8) If the first response is negative, ten more squeezes are repeated rapidly and the test subject is again asked whether the Bitrex is tasted.

(9) If the second response is negative, ten more squeezes are repeated rapidly and the test subject is again asked whether the Bitrex is tasted.

(10) The test conductor will take note of the number of squeezes required to solicit a taste response.

(11) If the Bitrex is not tasted after 30 squeezes (step 10), the test subject may not perform the Bitrex fit test.

(12) If a taste response is elicited, the test subject shall be asked to take note of the taste for reference in the fit test.

(13) Correct use of the nebulizer means that approximately 1 ml of liquid is used at a time in the nebulizer body.

(14) The nebulizer shall be thoroughly rinsed in water, shaken to dry, and refilled at least each morning and afternoon or at least every four hours.

(b) Bitrex solution aerosol fit test procedure.

(1) The test subject may not eat, drink (except plain water), smoke, or chew gum for 15 minutes before the test.

(2) The fit test uses the same enclosure described in (a) above.

(3) The test subject shall don the enclosure while wearing the respirator selected in section I.A. of this appendix. The respirator shall be properly adjusted and equipped with a particulate filter(s).

(4) A second nebulizer device such as a DeVilbiss Model 40 Inhalation Medication Nebulizer or equivalent is used to spray the fit test solution into the enclosure. This nebulizer shall be clearly marked to distinguish it from the screening test solution nebulizer.

(5) The fit test solution is prepared by adding 337.5 mg of Bitrex in 200 ml of a 5% solution of NaCl in warm water.

(6) As before, the test subject shall breathe through his or her slightly open mouth with tongue extended.

(7) The nebulizer is inserted into the hole in the front of the enclosure and the fit test solution is sprayed into the enclosure using the same number of squeezes required to elicit a taste response in the screening test.

(8) After generating the aerosol the test subject shall be instructed to perform the exercises in section I.A.13 of this appendix.

(9) Every 30 seconds the aerosol concentration shall be replenished using half the number of squeezes as initially.

(10) The test subject shall indicate to the test conductor if at any time during the fit test the taste of Bitrex is detected.

(11) If the taste of Bitrex is detected, the fit is deemed unsatisfactory and a different respirator shall be tried.

5. Irritant Fume Protocol

(a) The respirator to be tested shall be equipped with high-efficiency particulate filters (i.e., HEPA, N100, R100, or P100) .

(b) No form of test enclosure or hood for the test subject shall be used.

(c) The test subject shall be allowed to smell a weak concentration of the irritant smoke before the respirator is donned to become familiar with its irritating properties.

(d) Break both ends of a ventilation smoke tube containing stannic chloride. Attach one end of the smoke tube to an aspirator squeeze bulb and cover the other end with a short piece of tubing to prevent potential injury from the jagged end of the smoke tube.

(e) Advise the test subject that the smoke can be irritating to the eyes and instruct the subject to keep his or her eyes closed while the test is performed.

(f) The test conductor shall direct the stream of irritant smoke from the smoke tube towards the face seal area of the test subject beginning at least 12 inches from the facepiece and gradually moving to within one inch, moving around the whole perimeter of the mask.

(g) The exercises identified in section I.A. 13 above shall be performed by the test subject while the respirator seal is being challenged by the smoke.

(h) Each test subject passing the smoke test without evidence of a response (involuntary cough) shall be given a sensitivity check of the smoke from the same tube once the respirator has been removed to determine whether he or she reacts to the smoke. Failure to evoke a response shall void the fit test.

(i) The fit test shall be performed in a location with exhaust ventilation sufficient to prevent general contamination of the testing area by the test agent.

C. Quantitative Fit Test (QNFT) Protocols

The following quantitative fit testing procedures have been demonstrated to be acceptable:

(1) Quantitative fit testing using a non-hazardous challenge aerosol (such as corn oil or sodium chloride) generated in a test chamber, and employing instrumentation to quantify the fit of the respirator.

(2) Quantitative fit testing using ambient aerosol as the challenge agent and appropriate instrumentation (condensation nuclei counter) to quantify the respirator fit.

(3) Quantitative fit testing using controlled negative pressure and appropriate instrumentation to measure the volumetric leak rate of a facepiece to quantify the respirator fit.

1. General

(a) The employer shall assign specific individuals who shall assume full responsibility for implementing the respirator quantitative fit test program.

(b) The employer shall ensure that persons administering QNFT are able to calibrate equipment and perform tests properly, recognize invalid tests, calculate fit factors properly and assure that test equipment is in proper working order.

(c) The employer shall assure that QNFT equipment is kept clean, maintained and calibrated according to the manufacturer's instructions so as to operate at the parameters for which it was designed.

2. Generated Aerosol Protocol

(a) *Apparatus.* (1) Instrumentation. Aerosol generation, dilution, and measurement systems using particulates (corn oil or sodium chloride) or gases or vapors as test aerosols shall be used for quantitative fit testing.

(2) *Test chamber.* The test chamber shall be large enough to permit all test subjects to perform freely all required exercises without disturbing the challenge agent concentration or the measurement apparatus. The test chamber shall be equipped and constructed so that the challenge agent is effectively isolated from the ambient air, yet uniform in concentration throughout the chamber.

(3) When testing air-purifying respirators, the normal filter or cartridge element shall be replaced with a high-efficiency particulate filter (i.e., HEPA, N100, R100, P100) supplied by the same manufacturer in the case of particulate QNFT aerosols or a sorbent offering contaminant penetration protection equivalent to high-efficiency filters where the QNFT test agent is a gas or vapor.

(4) The sampling instrument shall be selected so that a computer record or strip chart record may be made of the test showing the rise and fall of the challenge agent concentration with each inspiration and expiration at fit factors of at least 2,000. Integrators or computers that integrate the amount of test agent penetration leakage into the respirator for each exercise may be used, provided a record of the readings is made.

(5) The combination of substitute air-purifying elements, challenge agent and challenge agent concentration shall be such that the test subject is not exposed in excess of an established exposure limit for the challenge agent at any time during the testing process based upon the length of the exposure and the exposure limit duration.

(6) The sampling port on the test specimen respirator shall be placed and constructed so that no leakage occurs around the port (e.g. where the respirator is probed), a free air flow is allowed into the sampling line at all times and so that there is no interference with the fit or performance of the respirator. The in-mask sampling device (probe) shall be designed and used so that the air sample is drawn from the breathing zone of the test subject, midway between the nose and mouth and with the probe extending into the facepiece cavity at least ¼ inch.

(7) The test set-up shall permit the person administering the test to observe the test subject inside the chamber during the test.

(8) The equipment generating the challenge atmosphere shall maintain the concentration of challenge agent constant to within a 10 percent variation for the duration of the test.

(9) The time lag (interval between an event and the recording of the event on the strip chart or computer or integrator) shall be kept to a minimum. There shall be a clear association between the occurrence of an event and its being recorded.

(10) The sampling line tubing for the test chamber atmosphere and for the respirator sampling port shall be of equal diameter and

of the same material. The length of the two lines shall be equal.

(11) The exhaust flow from the test chamber shall pass through an appropriate filter (i.e., high efficiency or sorbent) before release.

(12) When sodium chloride aerosol is used, the relative humidity inside the test chamber shall not exceed 50 percent.

(13) The limitations of instrument detection shall be taken into account when determining the fit factor.

(14) Test respirators shall be maintained in proper working order and inspected for deficiencies such as cracks, missing valves and gaskets, etc.

(b) *Procedural Requirements.* (1) When performing the initial positive or negative pressure fit check, the sampling line shall be crimped closed in order to avoid air pressure leakage during either of these fit checks.

(2) An abbreviated screening QLFT test may be utilized in order to quickly identify poor fitting respirators which passed the positive and/or negative pressure test and thus reduce the amount of QNFT time. The use of the CNC QNFT instrument in the count mode is another method that can be used to obtain a quick estimate of fit and eliminate poor fitting respirators before going on to perform a full QNFT.

(3) A reasonably stable challenge agent concentration shall be measured in the test chamber prior to testing. For canopy or shower curtain type of test units the determination of the challenge agent stability may be established after the test subject has entered the test environment.

(4) Immediately after the subject enters the test chamber, the challenge agent concentration inside the respirator shall be measured to ensure that the peak penetration does not exceed 5 percent for a half mask or 1 percent for a full facepiece respirator.

(5) A stable challenge concentration shall be obtained prior to the actual start of testing.

(6) Respirator restraining straps shall not be over tightened for testing. The straps shall be adjusted by the wearer without assistance from other persons to give a reasonable fit typical of normal use.

(7) The test shall be terminated whenever any single peak penetration exceeds 5 percent for half masks and 1 percent for full facepiece respirators. The test subject shall be refitted and retested.

(c) *Calculation of fit factors.* (1) The fit factor shall be determined for the quantitative fit test by taking the ratio of the average chamber concentration to the concentration measured inside the respirator for each test exercise except the grimace exercise.

(2) The average test chamber concentration shall be calculated as the arithmetic average of the concentration measured before and after each test (i.e., 8 exercises) or the arithmetic average of the concentration measured before and after each exercise or the true average measured continuously during the respirator sample.

(3) The concentration of the challenge agent inside the respirator shall be determined by one of the following methods:

(i) Average peak penetration method, which is the method of determining test agent penetration into the respirator utilizing a strip chart recorder, integrator, or computer. The agent penetration is determined by an average of the peak heights on the graph or by computer integration, for each exercise except the grimace exercise. Integrators or computers that calculate the actual test agent penetration into the respirator for each exercise also meet the requirements of the average peak penetration method.

(ii) Maximum peak penetration method means the method of determining test agent penetration in the respirator as determined by strip chart recordings of the test. The highest peak penetration for a given exercise is taken to be representative of average penetration into the respirator for that exercise.

(iii) Integration by calculation of the area under the individual peak for each exercise except the grimace exercise is another method. This includes computerized integration.

(iv) The calculation of the overall fit factor using individual exercise fit factors involves first converting the exercise fit factors to penetration values, determining the average, and then converting that result back to a fit factor is also appropriate. This procedure is described in the following equation:

$$\text{Overall Fit Factor} = \frac{\text{Number of exercises}}{1/ff_1 + 1/ff_2 + 1/ff_3 + 1/ff_4 + 1/ff_5 + 1/ff_6 + 1/ff_7 + 1/ff_8}$$

Where ff_1, ff_2, ff_3, etc. are the fit factors for exercise 1,2,3, etc.

(4) The test subject shall not be permitted to wear a half mask or quarter facepiece respirator unless a minimum fit factor of 100 is obtained, or a full facepiece respirator unless a minimum fit factor of 500 is obtained.

(5) Filters used for quantitative fit testing shall be replaced whenever increased breathing resistance is encountered, or when the test agent has altered the integrity of the filter media. Organic vapor cartridges/canisters shall be replaced if there is any indication of breakthrough by a test agent.

3. Ambient Aerosol Condensation Nuclei Counter (CNC) Protocol

The ambient aerosol condensation nuclei counter (CNC) quantitative fit testing (Portacount™) protocol quantitatively fit tests respirators with the use of a probe. The probed respirator is only used for quantitative fit tests. A probed respirator has a special sampling device, installed on the respirator, that allows the probe to sample the air from inside the mask. A probed respirator is required for each make, model, and size that is intended to be used and can be obtained from the respirator manufacturer or distributor. The CNC instrument manufacturer TSI also provides probe attachments (TSI sampling adapters) that permit fit testing in an employee's own respirator. A minimum fit factor pass level of 100 is necessary for a half-mask respirator and a minimum fit factor of at least 500 is required for a full facepiece respirator. The Agency does not recommend the use of homemade sampling adapters. The entire screening and testing procedure shall be explained to the test subject prior to the conduct of the screening test.

(a) Portacount Fit Test Requirements.

(1) Check the respirator to make sure the respirator is fitted with a high efficiency filter (i.e., HEPA, N100, R100, P100) and that the sampling probe and line are properly attached to the facepiece.

(2) Instruct the person to be tested to don the respirator several minutes before the fit test starts. This purges the particles inside the respirator and permits the wearer to make certain the respirator is comfortable. This individual should have already been trained on how to wear the respirator properly.

(3) Check the following conditions for the adequacy of the respirator fit: Chin properly placed; Adequate strap tension, not overly tightened; Fit across nose bridge; Respirator of proper size to span distance from nose to chin; Tendencies for the respirator to slip; Self-observation in a mirror to evaluate fit; and respirator position.

(4) Have the person wearing the respirator do a fit check. If leakage is detected, determine the cause. If leakage is from a poorly fitting facepiece, try another size of the same type of respirator.

(5) Follow the instructions for operating the Portacount and proceed with the test.

(b) *Portacount Test Exercises*—(1) *Normal breathing.* In a normal standing position, without talking, the subject shall breathe normally for 1 minute.

(2) *Deep breathing.* In a normal standing position, the subject shall breathe slowly and deeply for 1 minute, taking caution so as not to hyperventilate.

(3) *Turning head side to side.* Standing in place, the subject shall slowly turn his or her head from side to side between the extreme positions on each side for 1 minute. The head shall be held at each extreme momentarily so the subject can inhale at each side.

(4) *Moving head up and down.* Standing in place, the subject shall slowly move his or her head up and down for 1 minute. The subject shall be instructed to inhale in the up position (i.e., when looking toward the ceiling).

(5) *Talking.* The subject shall talk out loud slowly and loud enough so as to be heard clearly by the test conductor. The subject can read from a prepared text such as the Rainbow Passage, count backward from 100, or recite a memorized poem or song for 1 minute.

(6) *Grimace.* The test subject shall grimace by smiling or frowning for 15 seconds.

(7) *Bending Over.* The test subject shall bend at the waist as if he or she were to touch his or her toes for 1 minute. Jogging in place shall be substituted for this exercise in those test environments such as shroud type QNFT units that prohibit bending at the waist.

(8) *Normal Breathing.* Remove and re-don the respirator within a one-minute period. Then, in a normal standing position, without talking, the subject shall breathe normally for 1 minute.

After the test exercises, the test subject shall be questioned by the test conductor regarding the acceptability of the respirator upon completion of the protocol. If it has become unacceptable, another model of respirator shall be tried.

(c) *Portacount Test Instrument.* (1) The Portacount will automatically stop and calculate the overall fit factor for the entire set of exercises. The overall fit factor is what counts. The Pass or Fail message will indicate whether or not the test was successful. If the test was a Pass, the fit test is over.

(2) A record of the test needs to be kept on file assuming the fit test was successful. The record must contain the test subject's name; overall fit factor; make, model and size of respirator used, and date tested.

4. Controlled Negative Pressure (CNP) Protocol

The CNP protocol provides an alternative to aerosol fit test methods. The CNP fit test method technology is based on exhausting air from a temporarily sealed respirator facepiece to generate and then maintain a constant negative pressure inside the facepiece. The rate of air exhaust is controlled so that a constant negative pressure is maintained in the respirator during the fit test. The level of pressure is selected to replicate the mean inspiratory pressure that causes leakage into the respirator under normal use conditions. With pressure held constant, air flow out of the respirator is equal to air flow into the respirator. Therefore, measurement of the exhaust stream that is required to hold the pressure in the temporarily sealed respirator constant yields a direct measure of leakage air flow into the respirator.

The CNP fit test method measures leak rates through the facepiece as a method for determining the facepiece fit for negative pressure respirators. The CNP instrument manufacturer Dynatech Nevada also provides attachments (sampling manifolds) that replace the filter cartridges to permit fit testing in an employee's own respirator. To perform the test, the test subject closes his or her mouth and holds his or her breath, then an air pump removes air from the respirator facepiece at a pre-selected constant pressure. The facepiece fit is expressed as the leak rate through the facepiece, expressed as milliliters per minute. The quality and validity of the CNP fit tests are determined by the degree to which the in-mask pressure tracks the challenge pressure during the system measurement time of approximately five seconds. Instantaneous feedback in the form of a real-time pressure trace of the in-mask pressure is provided and used to determine test validity and quality. A minimum fit factor pass level of 100 is necessary for a half-mask respirator and a minimum fit factor of at least 500 is required for a full facepiece respirator.

The entire screening and testing procedure shall be explained to the test subject prior to the conduct of the screening test.

(a) *CNP Fit Test Requirements*—(1) The instrument shall have a non-adjustable challenge pressure of 15.0 mm water pressure.

(2) The CNP system defaults for challenge pressure shall be tested at −0.58 inches of water and the modeled inspiratory flow rate shall be 53.8 liters per minute.

Note: CNP systems have built-in capability to conduct fit testing that is specific to unique work rate, mask, and gender situations that might apply in a specific workplace. Use of system default values, which were selected to represent respirator wear with medium cartridge resistance at a low-moderate work rate, will allow inter-test comparison of the respirator fit.

(3) The individual who conducts the CNP fit testing shall be thoroughly trained to perform the test.

(4) The respirator filter or cartridge needs to be replaced with the CNP test manifold. The inhalation valve downstream from the manifold either needs to be temporarily removed or propped open.

(5) The test subject shall be trained to hold his or her breath for at least 20 seconds.

(6) The test subject shall don the test respirator without any assistance from the individual who conducts the CNP fit test.

(7) The QNFT protocol shall be followed according to section I.C.1 except that the CNP test exercises shall be used.

(b) *CNP Test Exercises*—(1) *Normal breathing.* In a normal standing position, without talking, the subject shall breathe normally for 1 minute. After the normal breathing exercise, the subject needs to hold head straight ahead and hold his or her breath for 10 seconds during the test measurement.

(2) *Deep breathing.* In a normal standing position, the subject shall breathe slowly and deeply for 1 minute, taking caution not to hyperventilate. After the deep breathing exercise, the subject needs to hold head straight ahead and hold his or her breath for 10 seconds during test measurement.

(3) *Turning head side to side.* Standing in place, the subject shall slowly turn his or her head from side to side between the extreme positions on each side for 1 minute. The head shall be held at each extreme momentarily so the subject can inhale at each side. After the turning head side to side exercise, the subject needs to hold head full left and hold his or her breath for 10 seconds during test measurement. Next, the subject needs to hold head full right and hold his or her breath for 10 seconds during test measurement.

(4) *Moving head up and down.* Standing in place, the subject shall slowly move his or her head up and down for 1 minute. The subject shall be instructed to inhale in the up position (i.e., when looking toward the ceiling). After the moving head up and down exercise, the subject needs to hold head full up and hold his or her breath for 10 seconds during test measurement. Next, the subject needs to hold head full down and hold his or her breath for 10 seconds during test measurement.

(5) *Talking.* The subject shall talk out loud slowly and loud enough so as to be heard clearly by the test conductor. The subject can read from a prepared text such as the Rainbow Passage, count backward from 100, or recite a memorized poem or song for 1 minute. After the talking exercise, the subject needs to hold his or her head straight ahead and hold his or her breath for 10 seconds during the test measurement.

(6) *Grimace.* The test subject shall grimace by smiling or frowning for 15 seconds. After the grimace exercise, the subject needs to hold his or her head straight ahead and hold his or her breath for 10 seconds during the test measurement.

(7) *Bending Over.* The test subject shall bend at the waist as if he or she were to touch his or her toes for 1 minute. Jogging in place shall be substituted for this exercise in those test environments such as shroud type QNFT units that prohibit bending at the waist. After the bending over exercise, the subject needs to hold his or her head straight ahead and hold his or her breath for 10 seconds during the test measurement.

(8) *Normal Breathing.* Remove and re-don the respirator within a one-minute period. Then, in a normal standing position, without talking, the subject shall breathe normally for 1 minute. After the normal breathing exercise, the subject needs to hold his or her head straight ahead and hold his or her breath for 10 seconds during the test measurement.

After the test exercises, the test subject shall be questioned by the test conductor regarding the acceptability of the respirator upon completion of the protocol. If it has become unacceptable, another model of a respirator shall be tried.

(c) *CNP Test Instrument.*—(1) The test instrument shall have an effective audio warning device when the test subject fails to hold his or her breath during the test. The test shall be terminated whenever the test subject failed to hold his or her breath. The test subject may be refitted and retested.

(2) A record of the test needs to be kept on file, assuming the fit test was successful. The record must contain the test subject's name; overall fit factor; make, model and size of respirator used, and date tested.

Part II. Facepiece Fit Checks (Nonmandatory)

A. *Positive pressure check.* Close off the exhalation valve and exhale gently into the facepiece. The face fit is considered satisfactory if a slight positive pressure can be built up inside the facepiece without any evidence of outward leakage of air at the seal. For most respirators this method of leak testing requires the wearer to first remove the exhalation valve cover before closing off the exhalation valve and then carefully replacing it after the test.

B. *Negative pressure check.* Close off the inlet opening of the canister or cartridge(s) by covering with the palm of the hand(s) or by replacing the filter seal(s), inhale gently so that the facepiece collapses slightly, and hold

the breath for ten seconds. If the facepiece remains in its slightly collapsed condition and no inward leakage of air is detected, the tightness of the respirator is considered satisfactory.

Appendix C to § 1910.1035—Ventilation Chart for Isolation Rooms or Areas (Mandatory)

Under paragraph(d)(5)(vii), the proposed standard requires that when an AFB isolation room or area is vacated by an individual with suspected or confirmed infectious TB, the room or area shall be ventilated according to current CDC recommendations for a removal efficiency of 99.9% before permitting employees to enter without respiratory protection. The following appendix is an excerpt of the CDC recommendations of the air changes per hour (ACH) and time in minutes required for removal efficiencies of 90%, 99% and 99.9% of airborne contaminants (Ex.4B). This table specifies the time necessary to ventilate an isolation room or area, for a given air change per hour, before allowing employees to enter without respiratory protection.

Minutes required for a removal efficiency of:

ACH	90%	99%	99.9%
1	138	276	414
2	69	138	207
3	46	92	138
4	35	69	104
5	28	55	83
6	23	46	69
7	20	39	59
8	17	35	52
9	15	31	46
10	14	28	41
11	13	25	38
12	12	23	35
13	11	21	32
14	10	20	30
15	9	18	28
16	9	17	26
17	8	16	24
18	8	15	23
19	7	15	22
20	7	14	21
25	6	11	17
30	5	9	14
35	4	8	12
40	3	7	10
45	3	6	9
50	3	6	8

This table has been adapted from the formula for the rate of purging airborne contaminants. (Ex. 5–100) Values have been derived from the formula $t_1 = [In (C_2 + C_2) + (Q + V)] \times 60$, with $t_1 = 0$ and $C_1 + C_2$—(removal efficiency + 100), and where:

t_1 = initial timepoint
C_1 = initial concentration of contaminants
C_2 = final concentration of contaminants
Q = air flow rate (cubic feet per hour)
V = room volume (cubic feet)
Q + V = ACH

The times given assume perfect mixing of air within the space (i.e., mixing factor = 1). However, perfect mixing usually does not occur, and the mixing factor could be as high as 10 if air distribution is very poor (Ex. 5–99). The required time is derived by multiplying the appropriate time for the table by the mixing factor that has been determined for the booth or room. The factor and required time should be included in the operating instructions provided by the manufacturer of the booth or enclosure, and these instructions should be followed.

Appendix D to § 1910.1035—Ultraviolet Radiation Safety and Health Provisions (Nonmandatory)

This appendix sets forth non-mandatory guidelines on safety and health provisions concerning the use of ultraviolet germicidal irradiation (UVGI). Because the effectiveness of UVGI systems will vary, and the interaction of factors such as humidity, UV intensity, duration of exposure, lamp placement, and air mixing have not been adequately evaluated, employers may choose to use UVGI systems as supplements to the administrative, engineering, and work practice controls required by this standard. OSHA does not consider UVGI as a substitute or replacement for:

(1) Negative pressure;

(2) Exhaust of contaminated air directly to the outside away from intake vents and employees;

(3) High efficiency particulate air (HEPA) filtration of contaminated air before being recirculated to the general facility or exhausted directly outside (permitted only when it cannot be safely discharged).

UVGI Systems

The intent of UVGI systems is to kill or inactivate airborne microorganisms, including *M. tuberculosis.* Two types of systems are generally employed for this purpose: duct irradiation systems, and upper room air irradiation systems. (Floor level UVGI systems are used in some laboratory facilities, but are not specifically discussed in this appendix.) UVGI systems utilize low-pressure mercury vapor lamps that emit radiant energy predominantly at a wavelength of 254 nanometers (nm).[1] In duct irradiation systems, one or more UV tubes are positioned within a duct to irradiate air being exhausted from a room or facility. In upper room air irradiation systems, UV lamps are suspended from a ceiling or mounted on a wall. The lamps are positioned such that air in the upper part of the room is irradiated. The intent is to minimize the levels of UV radiation in the lower part of the room where the occupants are located. These systems rely on air mixing to move the air from the lower portion of the room to the upper portion of the room where it can be irradiated.

Safety and Health Considerations

UV radiation at 254 nm is absorbed by the outer surfaces of the eyes and skin. Overexposure to UVGI can result in photokeratitis (inflammation of the cornea) and/or conjunctivitis (inflammation of the conjunctiva).[2] Keratoconjunctivitis is a reversible condition but can be debilitating while it runs its course. Because there is a latency period before health effects are observed, workers may not recognize this as an occupational injury. Symptoms may include a feeling of sand in the eyes, tearing, and sensitivity to light. Overexposure of the skin to UVGI also can result in erythema (reddening). This effect is also reversible, with recovery occurring within 2 to 3 days.

In 1992, the International Agency for Research on Cancer (IARC) classified UV–C radiation as ''probably carcinogenic to humans (Group 2A)''.[3] This classification was based on studies suggesting that UV–C radiation can induce skin cancers in animals, DNA and chromosome damage in human cells in vitro, and DNA damage in mammalian skin cells in vivo. In the animal studies, exposure to UV–B could not be excluded; however, the observed effects were greater than expected for UV–B alone.[3] Laboratory studies have shown that UV radiation can activate human immunodeficiency virus (HIV) gene promoters in human cells (genes in HIV that prompt replication of the virus); however, the implications of these findings for humans exposed to UVGI are unknown.[4,5,6,7,8,9]

Occupational Exposure Criteria for Ultraviolet Radiation

In 1972, the National Institute for Occupational Safety and Health (NIOSH) published a recommended exposure limit (REL) for UV radiation to prevent adverse effects on the eyes and skin.[2] The NIOSH REL for UV radiation is wavelength dependent because different wavelengths of ultraviolet radiation have differing abilities to cause skin and eye effects. The American Conference of Governmental Industrial Hygienists (ACGIH) also has a Threshold Limit Value® for UV radiation that is identical to the REL in this spectral region.[10] It should be noted that photosensitive individuals and those concomitantly exposed to photosensitizing agents (including certain medications) may not be protected by these occupational exposure limits.[10]

The term relative spectral effectiveness is used to compare UV sources with a source producing UV radiation only at 270 nm, the wavelength of maximum sensitivity for corneal injury. For example, the relative spectral effectiveness (S_λ) at 254 nm is 0.5; therefore, twice as much energy is required at 254 nm to produce the same biological effect at 270 nm. Thus, at 254 nm, the NIOSH REL is 0.006 joules per square centimeter (J/cm^2), and at 270 nm it is 0.003 J/cm^2.

For germicidal lamps, proper use of the REL (or TLV) requires that the measured irradiance level (E) in microwatts per square centimeter (μW/cm^2) be multiplied by the relative spectral effectiveness at 254 nm (0.5) to obtain the effective irradiance (E_{eff}). The maximum permissible exposure time (t) for workers with unprotected eyes and skin can then be read directly from Table 1 for selected values of E_{eff}, or can be calculated (in seconds) by dividing 0.003 J/cm^2 (the NIOSH REL at 270 nm) by E_{eff} in W/cm^2. To protect workers who are exposed to germicidal UV radiation for eight hours per day, the measured irradiance (E), should be $\leq$0.2 μW/cm^2. This is calculated by using Table 1 to obtain E_{eff} (0.1 μW/cm^2), and then dividing by S_λ (0.5).

Example: If the measured irradiance was 0.4 μW/cm^2, then the maximum permissible exposure time is 15,000 seconds, or approximately 4 hours as shown below:

$$E_{eff} = E \times S_{\lambda}$$
$$= 0.4\ \mu W/cm^2 \times 0.5$$
$$= 0.2\ \mu W/cm^2$$
$$t\,(sec) = \frac{0.003\ J/cm^2}{E_{eff}\ \left(W/cm^2\right)}$$
$$= \frac{0.003\ J/cm^2}{0.2 \times 10^{-6}\ W/cm^2}$$
$$= 15{,}000\ sec.\ (approx\ 4\ hours)$$

TABLE 1—MAXIMUM PERMISSIBLE EXPOSURE TIMES FOR SELECTED VALUES OF E_{eff}.

Duration of exposure per day	Effective irradiance E_{eff} ($\mu W/cm^2$)
8 hrs	0.1
4 hrs	0.2
2 hrs	0.4
1 hr	0.8
30 min	1.7
15 min	3.3
10 min	5.0
5 min	10.0

This table was adapted from a table in *Criteria for a Recommended Standard . . . . Occupational Exposure to Ultraviolet Radiation.*[2] Maximum permissible exposure times refer to workers with unprotected eyes and skin.

Measurement Equipment. A UV radiometer can be used to measure the irradiance levels in the room and to document lamp output. Some UV measurement systems rely on the use of a detector or probe which is most sensitive at 254 nm, while others rely on the use of a broad-band radiometer with an actinic probe. The latter instrument has a response that accounts for the wavelength dependence of the REL, allowing direct measurement of the effective irradiance (E_{eff}).[11] While both types of systems are acceptable, persons performing the measurements should be aware of the differences so that the measurements obtained are appropriately compared with the recommended occupational exposure limits. Equipment used to measure UV radiation should be maintained and calibrated on a regular schedule, as recommended by the manufacturer.

UVGI Safety and Health Program

Employers should consult with persons having expertise in industrial hygiene, engineering, and/or health physics before designing and installing UVGI systems. In addition, the following guidelines should be used to protect workers from overexposure to UV radiation. These guidelines should be incorporated into a UVGI safety and health program. One person should be given responsibility for managing the program.

(1) Exposure Monitoring

a. *Upper Air Irradiation Systems.* Before an upper air UVGI system is activated in the workplace, exposure monitoring should be conducted to determine the levels of UV radiation in the room. The UV radiation levels will be affected by the position of the lamp, fixture design (including presence and position of baffles and louvers), tube type, room dimensions, and presence of UV absorbing or reflecting materials. At a minimum, UV radiation measurements should be made with the detector directly facing the lamp at head or eye height (with maximum levels recorded), to assess the potential UV exposure to the eyes, the most sensitive organ. Because workers typically move around a room or area while performing their duties, it is often not possible to predict how long a worker will be in a given location, nor is it practical to attempt to control exposures administratively by limiting the duration of exposure at a given location. Therefore, the exposure monitoring should be conducted in representative locations to adequately assess the range of potential worker exposures. Worker exposures should be maintained below the NIOSH REL[2] and ACGIH TLV[10] for ultraviolet radiation.

UV radiation measurements should be made: (1) at the time of initial installation of the UVGI system; (2) whenever new tubes are installed; and (3) whenever modifications are made to the UVGI system or to the room that may affect worker exposures (i.e., adjustment of fixture height, location, or position of louvers; addition of UV absorbing or reflecting materials; and changes in room dimensions).

UV radiation measurements may also be obtained to document the UV output of the lamp for tube replacement or other purposes. Because these types of measurements are commonly done close to the source of the UV output, the person obtaining the measurements may be exposed to high levels of UV radiation. UV radiation levels up to 840 $\mu W/cm^2$ (420 μ/cm^2 effective irradiance) have been measured at a distance of four inches from the face of a 30W tube that had been in use several months.[12] Using the NIOSH REL, this exposure level would result in a permissible exposure time of only 7 seconds for workers with unprotected eyes and skin. Because of the high irradiance levels, it would not be practical in this situation to control UV exposures by limiting exposure duration. Skin and eye protection would be needed to protect the worker when making UV measurements close to the source.

b. *Duct Irradiation Systems.* Duct irradiation systems frequently involve the placement of several UV tubes within a section of duct work. Thus, workers who have contact with these lamps are potentially exposed to high levels of UV radiation. This presents a hazard for maintenance workers and others who are responsible for documenting the UV output of these lamps. At one facility where a duct irradiation system was used, UV radiation levels up to 950 $\mu W/cm^2$ were measured at a distance of approximately three feet from a bank of four 39W UV tubes.[11] In this situation, the NIOSH REL would be exceeded in about 6 seconds; therefore, skin and eye protection would be needed to prevent worker overexposures to UV radiation. Most UV exposures resulting from duct irradiation systems can be avoided by inactivating the lamps before maintenance work is done, and providing an access port for viewing the lamps during preventive maintenance inspections. These control measures are discussed further in the Control Methods section of this appendix.

(2) Control Measures

The following control measures should be used to prevent or reduce UV exposures.

a. *Engineering Controls.* 1. In upper air irradiation systems, the UV tubes in the fixture should not be visible from any usual location/position in the room. The fixtures should contain baffles or louvers that are appropriately positioned to direct the UV irradiation to the upper air space. The baffles and louvers should be constructed so that they cannot be easily bent or deformed.

2. In upper air irradiation systems, all highly UV reflecting material should be removed, replaced, or covered. Reflectance values for various materials have been published.[13] Etched aluminum and chromium are examples of materials that have high reflectance values (88 and 45% reflectance, respectively) for 254 nm radiation. Unpainted white wall plaster is reported to have reflectance values of 40–60%.[13]

3. UV-absorbing paints (such as those containing titanium dioxide) can be used on ceilings and walls to minimize reflectance of UV in the occupied space, as needed.

4. The on/off switch for the UVGI lamps should not be located on the same switch as the general room lighting. In addition, these switches should be positioned in such a location that only authorized persons have access to them and they should be locked to ensure that they are not accidentally turned on or off.

5. In duct irradiation systems, there should be an access panel for conducting routine maintenance, monitoring, and cleaning. This access panel should have an interlock or other device to ensure that the tubes are deactivated whenever the panel is opened. To prevent unnecessary UV exposures to maintenance personnel, this port should have a window for viewing the tubes during routine inspections. Ordinary glass (not quartz) and plastics (polycarbonate and polymethylmethacrylate) are sufficient to filter out the UV radiation.[14]

6. All UVGI systems should be inactivated prior to maintenance activity in the affected areas, such as when maintenance workers replace lamps or when entering the upper air space for room maintenance, renovation, or repair work.

b. *Personal Protective Equipment.* UV exposures should be maintained below existing recommended levels. Despite the use of the engineering controls listed above, there may be situations when worker exposures exceed the NIOSH REL, such as when UV measurements are being made close to the lamp source in order to document lamp output, or when maintenance procedures must be performed in areas where UVGI systems are activated. In these and other situations where the NIOSH REL is exceeded, personal protective equipment is needed to prevent worker overexposure to UV radiation. This includes the use of UV-absorbing eyewear with side-shields, head,

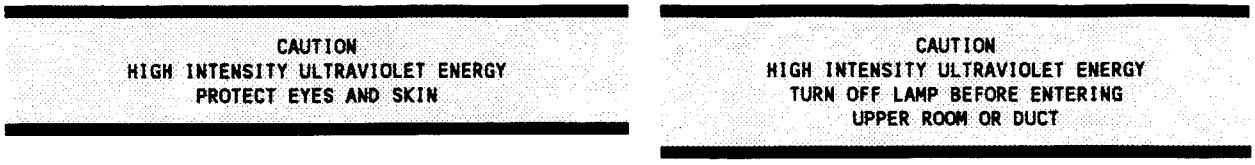
neck, and face covering opaque to UV radiation, gloves, and long-sleeved garments. The weave of the fabric has been shown to be the major factor affecting transmission of UV radiation,[15] thus, tightly woven fabrics are recommended. UV-absorbing sunscreens with solar-protection factors of 15 or higher may help protect photosensitive persons.[16]

(3) Labeling

Warning labels should be placed on UV lamp fixtures in upper air irradiation systems and on access panels in duct irradiation systems to alert workers and other room occupants to this potential hazard. These warning labels should be of sufficient size to be visible to room occupants and should be in the appropriate language(s). Examples of warning labels are shown below:

BILLING CODE 4510–26–P

BILLING CODE 4510–26–C



(4) Training

All workers who have potential exposure to UV radiation from UVGI systems should be receiving training on the hazards, relevant symptoms, and precautions concerning exposure. This training should include specific information on:

a. The rationale for use of UVGI and general principles of operation, including its limitations;

b. Control measures used to prevent or reduce UV radiation exposure;

c. Health effects associated with overexposure to UV radiation (including the potential for additive exposure from other UV sources, such as solar radiation and welding);

d. Recognition of the symptoms of eye and skin damage; and

e. Special precautions to be taken by workers to prevent overexposure to UV radiation (including the use of personal protective equipment).

(5) Medical Recommendations

The worker's medical history should be obtained to determine if the worker suffers from any condition that may be exacerbated by exposure to UV radiation. Workers should be advised that any eye or skin irritation that develops after acute exposure to UV radiation, or any skin lesion that appears on skin repeatedly exposed to UV radiation should be examined by a physician.

(6) Recordkeeping

The employer should maintain accurate and complete records pertaining to the following:

a. Exposure monitoring;

b. Instrument calibration;

c. Documentation of health effects;

d. Training;

e. Maintenance of UVGI systems, including cleaning and replacement of tubes.

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Appendix E to § 1910.1035—Performance Monitoring Procedures for HEPA Filters (Nonmandatory)

This appendix offers nonmandatory guidance on design considerations and performance monitoring of HEPA filters used in air systems that carry air that may reasonably be anticipated to contain aerosolized *M. tuberculosis* (e.g., recirculation into building circulating air system, exhausting outdoors near air intakes, etc.).

Both OSHA and CDC recommend against the recirculation of air that may reasonably be anticipated to contain aerosolized *M. tuberculosis* into the general circulating air system of the building or other opportunities where such air may become entrained into the circulating air system (e.g., outdoor exhausting near intakes, transfer to heat wheels, etc.). When recirculation is unavoidable, the air should be cleaned with HEPA filtration. In order to assure effective functioning of these systems, they should be properly designed, installed, and maintained.

Design of HEPA Filtration Systems

The following elements should be considered for incorporation into the design of HEPA filtration systems:

1. Provide upstream prefiltering to reduce dust that may plug the HEPA filter.

2. Provide worker-entry into housings for visual examinations and probe scanning for leaks of filter media and frame-to-filter interfaces. In addition, adequate access should be provided to allow for replacement of the HEPA filters and pre-filters without contaminating the work area by unintentional jarring or dropping of the filters.

3. Provide devices for measuring HEPA filter loading (e.g., pressure differential across a filter).

4. Provide appropriate mounting frames and seals to minimize frame-to-filter leakage.

5. Specify filter media to match operating criteria (e.g., face velocity, volumetric flow rate, pressure drop, etc.).

6. Design upstream and downstream duct to facilitate performance monitoring (e.g., good air mixing for uniform dispersal of challenge aerosols, sectioning to allow isolation of leaks, etc.).

7. HEPA filters must operate in dry airstreams. Tests have shown that exposure

to high humidity for a period of five hours will result in a threefold increase in particle penetration.

Maintenance of HEPA Filtration Systems

HEPA filtration systems are generally passive systems without moving parts, so the majority of filter maintenance activities are associated with performance monitoring. In terms of performance monitoring, HEPA filters are to be monitored for *filter loading* and for possible *leakage* every 6 months, whenever filters are changed, and more often if necessary to maintain effectiveness. Leaks in HEPA filters can occur in the following ways: (1) in the filter media, (2) in the bond between media and frame, (3) in the frame gasket, (4) in the support frame, and (5) in between the frame and the wall.

Testing of HEPA filters after installation is used to detect leaks associated with shipping damage and with installation problems such as handling damage, variations in gasket thickness and poorly formed gasket corners.

Periodic testing detects deterioration of components, relaxation of gaskets, clamping devices, weld cracks or other leaks that may develop during use. This deterioration will take place even if the system is not on-line and in use.

Monitoring for Filter Loading

HEPA filtration systems become loaded with particulate matter through use. Although this loading improves particulate arrestance, it eventually increases the pressure drop across the filter assembly. Consequently, the flow capacity begins to diminish and bypass leakage at the frame-to-filter interface increases. Therefore, these filters need to be monitored and changed.

It is imperative that the differential pressures across the HEPA filter remain below the maximum operating resistance level set by the manufacturer and stamped on the filter label. Filter penetration by contaminants can occur when HEPA filters exceed the manufacturer's maximum resistance rating, making the system ineffective.

The operating resistance level is determined by measuring the pressure differential across the filter through use of a pressure sensing device. Measurements of differential pressure across the HEPA filters should be made when the prefilters have been removed. These measurements should be used to predict future HEPA filter replacement or for determining the need for immediate HEPA filter replacement.

Additional control measures can be used to detect a differential pressure that exceeds the maximum operating resistance which signals the alarm's set point (i.e., audible/visual alarms or computerized error messages).

All pressure measurements should be logged and retained in accordance with paragraph (i)(4)(ii) of this standard.

Monitoring for In-service Filter Leakage

In CDC's ''Guidelines for Preventing the Transmission of Mycobacterium tuberculosis in Health-Care Facilities'' [Ex. 4B], the di-octal phthalate (DOP) penetration test as described in Chapter 25 of the *1992 Systems Handbook from the American Society of Heating, Refrigerating and Air-Conditioning Engineers (ASHRAE)* is offered as a method of performance monitoring HEPA filters. The basis of this well-recognized test is to challenge a HEPA filter assembly with a uniformly distributed cloud of 0.3 µm (mass median diameter) DOP aerosol and measure the DOP smoke upstream and downstream with a light-scattering photometer. Penetration ''P'' through the filter assembly is the performance criterion typically specified and is defined as:

$$P = 100\left(\frac{\text{downstream concentration}}{\text{upstream concentration}}\right)\%$$

Penetration is related to filter efficiency ''E'' by the equation:

$$E=100(1-P)\%$$

Therefore, an efficiency of 99.97% is equivalent to P=0.0003.

Other Filter Testing Methods

There are many recognized HEPA filter testing standards. Most of these standards utilize DOP aerosol to challenge the HEPA filters and provide penetration performance data for 0.3 µm size particles. Since TB droplet nuclei range in size from 1 to 5 µm, the DOP aerosol challenge is indicative of droplet nuclei penetration. Some manufacturers may provide bench test data for filtration efficiency versus particle size which may be useful information when selecting filters but may be difficult to duplicate in the field for in-service testing. These test standards include:

1. Standard UL 586, *High-Efficiency, Particulate, Air Filter Units* as published by Underwriters Laboratories, 1990 (Ex. 7–227). This test is designed for bench testing at the factory and does not include the frame-to-filter bypass leakage measured by in-service testing. This test method uses a light beam-photocell combination (photometer) to measure the density of the DOP smoke in the air.

2. Standard ASTM F1471–92, *Air Cleaning Performance of a High-Efficiency Particulate Air-Filter System,* as published by the American Society for Testing and Materials, 1993 (Ex. 7–222). This test can be used in the field for in-service testing of HEPA filters. This test method utilizes a laser aerosol spectrometer which can count particles by particle size.

3. Standard NSF–49, Appendix B, *HEPA Filter Leak Test for Biosafety Cabinets,* as published by the National Sanitation Foundation (Ex. 7–226). This test is designed for in-service HEPA filter testing and utilizes a portable photometer probe which can be passed over the filter frame perimeter to check for bypass leaks.

Unfortunately, there are hazards associated with exposure to DOP. The Material Safety Data Sheet for DOP reports irritation, nausea and numbness as symptoms associated with DOP inhalation. Nausea, diarrhea, reproductive effects, liver enlargement, and cancer are effects associated with ingestion of DOP. Therefore, performance testing that does not utilize DOP should also be considered.

Alternative methods are in use and being developed that capitalize on recently developed optical particle counters (e.g., lasers) that can count particles at specified sizes. For example, the National Environmental Balancing Bureau (NEBB) publishes *Procedural Standards for Certified Testing of Clean rooms'* Section 8.3 presents an *Ambient Particle Aerosol Challenge Method* that utilizes new-generation optical particle counters to measure upstream and downstream concentrations of particles of a specified size (Ex. 7–228). Only ambient air is measured and no aerosol is generated. This method may have merit for TB applications because ambient air has a statistically significant quantity of particles less than 3.0 µm, but at the same time, this high number of particles may overload the instrument.

Because a dark DOP smoke is not required to attenuate light as is the case with a photometer, recently developed optical particle counters offer the opportunity for an alternative non-toxic challenge aerosol like that described in the proposed Standard 52.2 *Method of Testing General Ventilation Air-Cleaning Devices for Removal Efficiency by Particle Size* from the American Society of Heating, Refrigerating and Air-Conditioning Engineers. This non-toxic challenge aerosol is based upon potassium chloride (KC) particles which are generated in the 0.3 to 10 µm size range (Ex. 7–224).

Filter Testing Performance Criteria

The following should be considered when setting performance testing criteria: (1) Failure of a HEPA filter in a recirculating air system can have serious consequences; (2) HEPA filters are more efficient in removing droplet nuclei than DOP due to the larger particle size of droplet nuclei; (3) In-service filter penetration testing should match factory testing that is P≤ 0.0003 for 0.3µm challenge particle; (4) The differential pressure drop across a HEPA filter from dirt loading should never exceed the maximum operating resistance set by the manufacturer and stamped on the filter label; (5) Penetration should not exceed 0.0001 when performing localized penetration scanning with a photometer probe around filter frames and across the filter face.

Appendix F to § 1910.1035—A Guide to Writing an Exposure Control Plan (Non-mandatory)

A Guide to Writing an Exposure Control Plan is a non-mandatory appendix developed to assist employers in complying with § 1910.1035 Occupational Exposure to

Tuberculosis. This standard requires employers to have a written Exposure Control Plan (ECP) documenting procedures they use to control exposure to Tuberculosis (TB).

The following guide aids employers in writing the required ECP by reviewing the standard's requirements and providing examples of policy, narrative statements, and a ''fill-in-the-blank'' sample ECP. Before using this guide, employers will need to read the standard. Once familiar with the standard, they can use this appendix to develop a program specific to their facility.

Employers are not required to use the sample ECP included in this guide. They may develop their own format and may include the TB ECP in their overall infection control plan. However, the ECP must include all OSHA required information and all policies and procedures in the plan must be implemented whether the ECP is a separate plan or included in another document. If the TB elements are included in an overall infection control plan, the employer must develop an index referring the reader to their locations within that plan. Since the elements in the sample ECP are the minimum necessary to meet the standard's requirements, employers may enhance the sample with more comprehensive procedures if they wish.

OSHA developed the guide to help employers comply with the standard. The information contained in this Guide to Writing an Exposure Control Plan for Occupational Exposure to Tuberculosis is not considered to be a substitute for the OSH Act or any provisions of the OSHA Standard. It provides general guidance for a particular standards-related topic and should not be considered a legal authority for compliance with OSHA requirements. The reader should consult the OSHA standard in its entirety for specific compliance requirements.

Employers who have additional questions concerning this standard may contact the nearest OSHA office.

How to Use This Guide

A Guide to Writing An Exposure Control Plan has two components: Notes to the Employer and a Sample Exposure Control Plan. Notes to the Employer consists of explanations for some of the standard's ECP requirements, guidance about writing an ECP and information about practices common to a variety of employers. Notes to the Employer is organized to correspond chronologically to the Sample Exposure Control Plan.

The Sample Exposure Control Plan contains examples of policy statements and procedures. It has a number of sections and is organized in program development form. Although it does not always follow the exact sequence of the standard, all elements of the standard are included. Each section of the Sample ECP is cross-referenced to the specific provisions of the standard using the letter and numerical paragraph designation. The Sample ECP has blank spaces to be completed by the employer with site-specific information.

The standard provides a tiered approach to compliance. Not all provisions apply to all facilities. This approach accommodates facilities with varying factors. OSHA's sample ECP accommodates the difference between these types of facilities.

(1) The first tier is employers (other than the operators of a laboratory) that do not admit or provide medical services to individuals with suspected or confirmed infectious TB, have had no cases of confirmed TB in the past 12 months and are located in counties that in the past two years have had zero cases of confirmed infectious TB in one year and fewer than 6 cases of confirmed infectious TB in the other year. Work settings in this tier have presented minimal occupational exposure and therefore may choose to comply with only a limited number of provisions. (See Appendix A). Required elements for these facilities are underlined in the sample ECP. They include: procedures for exposure determination, prompt identification of individuals with suspected or confirmed infectious TB, exposure incident reporting, and procedures for referring individuals with suspected or confirmed TB to facilities with appropriate isolation capabilities.

Employers who wish to have a minimal exposure control plan as described in Appendix A must document the number of cases of tuberculosis reported in their county in the previous twelve month reporting period and the number of individuals with confirmed tuberculosis encountered in the facility in the previous twelve months.

(2) The second tier encompasses employers who use early identification and transfer procedures rather than admit individuals with suspected or confirmed infectious TB. They typically do not have AFB isolation rooms or autopsy rooms or conduct high-hazard procedures in their facility. These facilities can omit the sections about AFB isolation rooms and engineering controls since these provisions do not apply to them unless they have to use temporarily isolate when it is not possible to transfer individuals with suspected or confirmed infectious TB within five hours. Paragraph (c)(2)(ii) lists the requirements of the ECP for this type of facility. In the sample ECP, certain sections are starred (*) to assist facilities that transfer individuals with suspected or confirmed infectious TB within five hours of discovery. These employers may omit the starred sections when writing their ECP.

(3) The third tier covers employers who admit and provide medical services to individuals with suspected or confirmed infectious TB. These employers are required to have AFB isolation rooms and procedures to protect employees working in or around those rooms. In addition, they must have maintenance schedules for engineering controls as well as other protections. Paragraph (c)(2)(iii) lists specific requirements for these facilities. However, if these employers transfer some individuals with suspected or confirmed infectious TB as well as admit and provide medical services for those individuals, the facility must have procedures for the transfer. The sample ECP includes all required ECP elements thus providing guidance to facilities that admit and provide medical services.

Sample Exposure Control Plan Notes to the Employer

Exposure Control Plan (c)(2)

Policies and Program Administration

The standard requires each employer to have a written exposure control plan and to review and update it annually. The Sample Exposure Control Plan has examples of statements reflecting the employer's policy. Blanks are provided for the employer to designate the facility name.

Employers have limited ECP provisions (see Appendix A) if they (1) do not admit or provide medical services to individuals with suspected or confirmed infectious TB, (2) have had no case of confirmed infectious TB in the past 12 months and (3) are located in a county that, in the past 2 years, has had zero cases of confirmed infectious TB reported in one year and fewer than 6 cases of confirmed infectious TB reported in the other year. (Paragraph (b)). In addition, these employers must determine the number of reported cases in the county for the last twelve month reporting period and record it in the ECP. They must also document the number of confirmed cases of TB in their facilities. The numbers can be recorded in this first section of the ECP.

The written ECP must be accessible to employees, OSHA and NIOSH representatives for viewing and copying as necessary. (Paragraph (c)(2)(vii)) A sample statement regarding the accessibility is written below. OSHA does not require this statement to be written. However, employers may include this type of statement in their ECP to clearly define the company's/organization's policy.

Sample Statement: Employees and/or OSHA or NIOSH representatives may view the ECP at _____ (location of ECP)_____ and may copy the plan as necessary.

Designating a specific person to be responsible for maintaining the exposure control plan is not a requirement of the regulation. However, it is a common practice.

Sample Statement: _____ (responsible person/department) _____ is responsible for maintaining, reviewing and updating the Exposure Control Plan (ECP).

Employee Exposure Determination (Paragraph (c)(1)(i)(A))

In paragraph (c)(1)(i) & (ii), OSHA requires employers to review job classifications in their facilities and determine which employees have occupational exposure to infectious TB (Occupational exposure is defined in paragraph (j) of the standard). All TB exposure determinations must be made without regard to the use of respiratory protection.

There are two basic employee job classifications for employers to consider: (1) jobs in which all employees have occupational exposure to infectious tuberculosis because of the very nature of the job such as respiratory therapists and nurses who work on a pulmonary unit and (2) jobs that result in occupational exposure to tuberculosis when certain tasks or procedures are performed; for example, dietary personnel delivering meals to an individual in AFB isolation or housekeeping staff cleaning an AFB isolation room.

All employees in the first job classification are considered to have occupational exposure to infectious TB, so specific job tasks for this classification are not required to be defined. In the second category, however, only some employees may have occupational exposure and , then, only when performing certain tasks. Therefore, OSHA requires the employer to define those tasks. Examples of tasks in which employees may have occupational exposure to TB include: transporting patients; entering occupied isolation areas to clean or deliver meals; performing maintenance on HVAC systems that exhaust air from occupied AFB isolation rooms; and, performing suctioning and/or aerosolized treatments on patients with suspected/confirmed TB. Tasks may be listed in closely related groups or as individual tasks.

Not all employers have both types of job classifications. Employers are not required to complete both categories unless there are job classifications that pertain to each.

Employee Notification of TB Hazards (Paragraph (c)(2)(i)(B))

The standard requires that the employer include procedures in the ECP ''for providing information about individuals with suspected or confirmed infectious TB or about air that may reasonably be anticipated to contain aerosolized *M. tuberculosis* to occupationally exposed employees who need this information in order to take proper precautions.''

The employer must assure that employees have enough information to take proper precautions against exposure to TB. However, the employer must also consider the medical confidentiality of the infectious individual and assure that this confidentiality is maintained to the extent possible and consistent with applicable laws.

Employers are expected to define responsibilities and outline procedures used to inform employees of TB hazards. OSHA requires that an employer notify employees by posting signs and labeling ventilation ducts. (Paragraphs (h) (1) & (2))

The following sample statements provide an abbreviated example of some procedures that might be used in a health care facility. These statements are not OSHA requirements but examples.

Sample Statement: As soon as infectious TB is suspected the nurse in charge of the unit must be informed. The nurse in charge of the unit also must assure that (1) the individual is placed in an AFB isolation room marked with a sign: ''No Admittance Without Wearing a Type N95 of More Protective Respirator'', (2) the nursing supervisor and infection control specialist are notified, (3) all staff working on the unit are notified, and (4) proper equipment is obtained.

If the individual with suspected or confirmed infectious TB must be transferred to be placed in an isolation room, all procedures required by this ECP will be utilized, such as masking the individual or if that cannot be done, having the employee don a respirator.

The nurse in charge of the unit immediately notifies the facility engineer to assure that (1) the engineering controls are working properly and (2) all maintenance and contract employees are informed of the potential TB hazard. _____ (maintenance engineer) _____ is to immediately check to assure that all ducts carrying exhaust air from the room occupied by the individual with suspected or confirmed infectious TB are labeled ''Contaminated air—Respiratory Protection Required''.

Dietary, laboratory, and other test order sheets are specially noted to indicate ''Respiratory Isolation—No admittance without an N95 or More Protective Respirator.''

In addition to informing their own employees, host employers are required to notify contractors of TB hazards. Some contractors and contracting employees may be required to enter or work in AFB isolation areas or other areas in the facility where occupational exposure is likely to occur or where air systems may reasonably be anticipated to contain aerosolized *M. tuberculosis.* Since host employers know the location of the hazards, they must inform the contractor. (Paragraph (d)(6))

OSHA requires the employer to post signs at the entrance to (1) rooms or areas used to isolate individuals with suspected or confirmed infectious TB, (2) areas where procedures or services are being performed on an individual with suspected or confirmed infectious tuberculosis and (3) clinical/research laboratories where *M. tuberculosis* is present. (Paragraph (h)(2))

Signs must include a picture of a stop sign, have a red background with white lettering and say: ''No Admittance Without Wearing a N95 or More Protective Respirator.'' The employer may include additional language provided the major message on the sign remains clear. (Paragraph (h)(2)(iii))

After the room is vacated, the sign must remain posted at the entrance until the room or area is ventilated, using the USPHS recommendations for removal efficiency of 99.9%, for the time necessary to permit entry without the use of a respirator. See Appendix C of the standard. (Paragraph (h)(2)(ii))

The room does not need to be ventilated and the sign may be removed immediately if both of the following criteria are met (1) the room was occupied by an individual with suspected infectious tuberculosis and (2) that individual is medically determined to be non-infectious. (Paragraph (h)(2)(ii))

If employers have engineering controls, those controls must be labeled appropriately and the labeling procedures must be noted in the ECP. (Paragraph (h)(1))

The type of HVAC system in the facility will determine where ducts are labeled. Ducts that have HEPA filtration must be labeled at all duct access points located prior to the HEPA filter. HVAC systems that exhaust air directly to the outside must be labeled at all access points, fans and exhaust outlets. (Paragraph (h)(1))

Signs at the entrance to clinical or research laboratories and autopsy suites must include the biohazard symbol, name of the laboratory director or other designated responsible person, *M. tuberculosis*, and special requirements for entering the laboratory or autopsy room. In addition, contaminated laboratory wastes must be labeled with the biohazard symbol or be placed in a red container. (Paragraph (h)(2)(iv))

Although the standard does not require noting this in the ECP, employers may want to document where engineering controls are located in their facility. If an employer chooses to note this, sample verbiage may be:

Sample Statement: _____ (list type of engineering controls in place)

_____

engineering controls are used in the Bronchoscopy suite located on the third floor of this building.

OR

There are no high-hazard procedures performed in this facility. There are no engineering controls in place.

Exposure Incident Reporting (Paragraph (c)(2)(i)(C))

The employer must investigate circumstances surrounding TB Skin Test conversions and exposure incidents to determine the cause and ways to make changes to prevent similar occurrences. (Paragraph (g)(4)(iv))

The procedures used to report and then to evaluate the incident must be included in this section of the ECP. In addition, employees are required to report incidents to a particular department or person. (Paragraph (c)(2)(i)(C)) This information must be included here, also.

Sample Statement: Exposure incidents are to be reported to _____ (name and department)

. _____

The reporting procedures utilized at __ (organization's name) __ are:

_____

_____

_____

Procedures for evaluating the circumstances surrounding the exposure incident at _____ (organization's name) _____ are:

_____

_____

_____

Prompt Identification of Individuals With Suspected or Confirmed Infectious TB (Paragraph (c)(2)(ii) & (iii)(A))

Each facility is required to establish procedures for promptly identifying individuals with suspected or confirmed infectious TB. The standard considers ''suspected or confirmed infectious TB'' to be:

''A potential disease state in which an individual is known or with reasonable diligence should be known, by the employer to have one or more of the following conditions, unless the individual's condition has been medically determined to result from a cause other than TB: (1) to be infected with *M. tuberculosis* and to have signs and symptoms of TB; (2) to have a positive acid fast bacilla (AFB) smear; or (3) to have a persistent cough lasting 3 or more weeks and two or more symptoms of active TB (e.g., bloody sputum, night sweats, weight loss, fever, anorexia)''. (Paragraph (j))

This definition must be included in the early identification criteria. Although not mandated by OSHA, some employers add high risk factors like IV drug use,

immunocompromised status, recent immigration from Asia, Africa, Latin America, etc.

Some employers use the *1994 CDC Guidelines for Preventing the Transmission of Mycobacterium Tuberculosis in Health-Care Facilities* to assist in early identification of TB (Ex. 4). These guidelines state, ''TB is not distributed evenly throughout all segments of the U.S. population'' and defines groups known to have a higher prevalence of TB infection. These high risk groups include ''foreign born persons from Asia, Africa, Latin America and the Caribbean; medically under served populations(e.g. some African-Americans, Hispanics, Asians, and Pacific Islanders, American Indians, and Alaskan Natives); homeless persons; current or former correctional-facility inmates; alcoholics; intravenous drug-users; and the elderly.'' Persons with certain medical conditions have a greater risk of progression from latent infection to active disease. These medical conditions are defined in the 1994 CDC guidelines as: ''HIV infection, silicosis, diabetes mellitus, gastrectomy or jejuno-ileal bypass, being greater than 10% below ideal body weight, chronic renal failure or renal dialysis, immuno-suppression due to drug therapy and some malignancies.''

There are several ways to conduct early identification. Many employers use a questionnaire to quickly assess the individual's health status at intake or admission. Some employers located in communities considered to have a high incidence of TB or working with high risk populations use chest x-rays. Since use of a questionnaire is a common practice, OSHA included one in the Sample ECP. This is not mandatory but is a guide for those employers who may wish to develop a questionnaire.

An example of a policy statement referring to use of a questionnaire is:

Sample Statement: ____ (organization's name) _____ uses the attached questionnaire to assess the individual's health status as related to suspected or confirmed infectious TB. An individual who has two or more of the symptoms of Tuberculosis in addition to a prolonged cough, a positive AFB smear or is known by ____ (organization's name) _____ or any of its employees to be infected with *M. tuberculosis* is categorized as having suspected or confirmed infectious TB.

Employers Who Transfer (Paragraph (c)(2)(ii))

Procedures for Transfer of Individuals With Suspected or Confirmed Tuberculosis

Employers that transfer rather than admit and provide medical services must document their procedures for isolating an individual while awaiting transfer such as segregating and masking the individual and procedures used if the individual cannot be transferred within 5 hours. This includes documenting the type of equipment used (e.g. masks, respirators).

In the remainder of the sample ECP, employers who transfer suspected or confirmed infectious TB within 5 hours of identification may omit starred sections if they do not have isolation rooms and engineering controls.

Employers who do not admit or provide medical services to individuals with suspected or confirmed infectious TB, have not encountered any individuals with confirmed TB in their facility in the past twelve months and who are located in counties that in the past two years have had zero cases of confirmed TB reported in one year and fewer than 6 cases in the other year and wish to claim reduced responsibilities must be prepared to transfer such individuals. Therefore, the standard requires these facilities to have procedures for transferring an individual with suspected or confirmed infectious TB, if encountered. (Appendix A)

Employers Who Admit and Provide Medical Services (Paragraph(c)(2)(iii))

Procedures for Isolating and Managing Care (Paragraph (c)(2)(iii)(B))

The employer must document procedures for isolating individuals with suspected or confirmed infectious TB such as using AFB isolation rooms and procedures for managing care to minimize employee exposure.

Procedures listed in the Sample ECP are limited to the standard requirements. Employers should add any other isolation and segregation procedures used in their facility to assure that their ECP reflects the way they manage isolation and segregation.

Employers who transfer individuals with suspected or confirmed infectious TB do not need to include procedures for isolating and managing care. However, as stated above, they must list procedures for transferring the individual and segregating and masking these individuals while awaiting transfer. In addition, employers who do not perform high hazard procedures in their facilities do not need to notate anything in the high hazard section of the ECP. These employers may wish to enhance their ECP by clarifying their functions, however. A sample of a statement to enhance and clarify is:

Sample Statement: (1) This facility transfers individuals with suspected or confirmed infectious TB within 5 hours of identification, (2) high-hazard procedures are not performed in this facility, (3) there are no engineering controls for TB control at this facility.

Again, the above statements are not OSHA requirements.

Each employer who admits or provides services to individuals with suspected or confirmed infectious TB is required to institute policies and procedures to address the following issues. The procedures in the Sample ECP are an abbreviated version of the OSHA requirements. (Paragraph (c)(2)(iii)(B) (1 through 5)):

- Minimizing the time the suspected/confirmed infectious individual spends outside the AFB isolation room.
- Minimizing the time of employee exposure in AFB isolation rooms or areas by combining as many tasks as possible into one entry.
- Minimizing the number of workers entering AFB isolation rooms.
- Using a properly fitted mask (e.g. surgical mask or valveless respirator) on individuals with suspected or confirmed infectious TB or transporting these individuals in portable containment engineering control when transport or relocation outside of AFB isolation rooms or areas is unavoidable.
- Delaying of elective transport or relocation.
- Providing services in an AFB isolation room or area to the extent feasible (e.g. portable x-ray).
- Assuring that the individual is returned to the isolation room as soon as is practical after the completion of the service or procedure.
- Delaying elective high-hazard procedures or elective surgery until the individual with suspected or confirmed infectious TB is determined to be non-infectious.

Some facilities may have extensive procedures while others may have less involved procedures. The extensiveness of the procedures is determined by the type of tasks and services provided the individual with suspected or confirmed infectious TB in that facility.

Whatever the procedures are, the employer is expected to assure that the procedures comply with the OSHA requirement and that all procedures are implemented.

*High-Hazard Procedures (Paragraph (c)(2)(iii)(C))

The ECP must contain a list of high-hazard procedures performed in the facility.

(*)All high-hazard procedures that may aerosolize *M. tuberculosis* must be performed in an AFB isolation room, an AFB isolation area, or in a special AFB containment booth. Examples of high hazard procedures include bronchoscopy, pulmonary function testing, endoscopy and autopsy on an individual with suspected or confirmed infectious TB.

*Engineering Controls Maintenance Schedules and Records (Paragraph (c)(2)(iii)(D))

Employers who have engineering controls in any part of their facility must include a maintenance and performance monitoring schedule in this section of the ECP. (Appendix E)

Sample Statement: Engineering controls for infectious TB are inspected, maintained and undergo performance monitoring according to the following schedule:

_____

_____

_____

Clinical and Research Laboratory Biosafety Procedures Paragraph (c)(2)(iv))

OSHA requires that the facility's laboratory director determine and document the biosafety level at which the laboratory operates.

In addition, the laboratory director must determine and document the need for (1) controlled access, (2) anterooms, (3) sealed windows, (4) directional airflow, (5) preventing recirculation of laboratory exhaust air, (6) filtration of exhaust air before discharge to the outside and (7) thimble exhaust connections for biological safety cabinets.

The laboratory director must consult and follow the guidelines found in the OSHA regulation.

Home Health Care or Home-Based Hospice Care (Paragraph (c)(2)(v))

OSHA requires employers of Home Care or Home-based Hospice care to include procedures for prompt identification of individuals with suspected or confirmed infectious TB. In addition procedures to minimize employee exposure to such individuals and a list of any high-hazard procedures performed in the home and procedures for delaying elective high hazards procedures or surgery until the individual is non-infectious must be included in the ECP.

Sample Exposure Control Plan

Exposure Control Plan (Paragraph(c)(2))

Policies and Program Administration

*(company name) maintains, reviews and updates the Exposure Control Plan (ECP) at least annually, and whenever necessary to reflect new or modified tasks, procedures and engineering controls * that affect occupational exposure. The ECP is also updated to reflect new or revised employee positions with occupational exposure.*

This facility has had _____ cases of confirmed TB in the last 12 months. (Paragraph (c)(2)(vi))

(b) This facility is located in _____ county which has reported cases of TB in the last twelve month reporting period.

Employee Exposure Determination (Paragraph (c)(2)(i)(A))

ALL employees in the following job classifications have or may have occupational exposure to TB (Paragraph(c)(1)(i)(A)): JOB TITLE

_____

_____

_____

Employees in the following job classifications have or may have exposure to TB when they are performing the listed tasks and procedures (Paragraph (c)(1)(B)):

JOB TITLE	TASKS/PROCEDURES

_____

_____

_____

Employee Notification of TB Hazard (Paragraph (c)(2)(i)(B))

(organization's name) uses the following procedures to assure that all employees with job tasks that offer potential for occupational exposure are informed of the hazard and take proper precautions against exposure to TB.

(procedures described)

_____

(*) _____ (responsible person(s)/department) _____ maintains contact with all outside contractors who provide temporary or contract employees who may incur occupational exposure. This allows the contractor to institute precautions to protect his or her employees. Theses contractors are informed of the TB hazard and the facility's procedures for protecting themselves from exposure.

(*) Signs are posted at the entrance to:

(*) 1) Rooms or areas used to isolate an individual with suspected or confirmed infectious TB,

(*) 2) Areas where procedures or services are being performed on an individual with suspected/confirmed infectious TB, and

(*) 3) clinical land research laboratories where M. tuberculosis is present.

(*) All signs are red with white text stating ''No Admittance Without a Type N95 of More Protective Respirator'' and have a picture of a stop sign. (See attached sample).

(*) _____ (organization's name) _____ ensures that warning labels are placed on AFB isolation room exhaust ducts and areas where occupational exposure to TB is expected.

(*) All systems carrying air that may be contain aerosolized M. Tuberculosis are labeled at all points where ducts are accessed prior to HEPA filter, at fans and at the discharge outlets of non-HEPA filtered direct discharge systems. The label says: ''Contaminated Air—Respiratory Protection Required''.

(*) ____ (organization's name) ____ notifies employees entering the laboratory and the autopsy room of the occupational hazards by using signs at the entrance to both these locations. These signs indicate the name and telephone number of the director of the laboratory, infectious agent—*M. tuberculosis,* and the special requirements for entering the laboratory or autopsy room. The sign displays the Biohazard symbol.

Exposure Incident Reporting (Paragraph (c)(2)(i)(C))

All employees must report exposure incidents immediately to (responsible person(s)/department). ____ (Organization's name) is responsible for investigating, evaluating, and documenting the circumstances surrounding the exposure incident for instituting changes to prevent similar occurrences.

The following procedures are used to investigate/evaluate exposure incidents at (organization's name):

_____

_____

_____

Prompt Identification of Individuals With Suspected or Confirmed Infectious TB (Paragraph (c)(2)(ii) and (iii)(A))

(Organization's name) considers an individual to be suspected of having Infectious TB (unless the individual's condition has been medically determined to result from a cause other than TB) if either the company or any of its employees determine(s)/learn(s)that the individual:

- *has a persistent cough lasting 3 or more weeks with 2 or more signs and symptoms of active infectious TB (e.g., bloody sputum, night sweats, weight loss, fever, anorexia),*
- *has a positive AFB smear,*

Based on the criteria listed above, (Organization's name) utilizes the following procedures for early detection of individuals with suspected/confirmed infectious TB.

_____

_____

_____

Employers Who Transfer (Paragraph(c)(2)(ii))

Procedures for Transfer of Individuals With Suspected or Confirmed Infectious TB:

If/when an isolation room is not available at our facility, the individual is transferred within 5 hours of identifying the infectivity to a facility (name of facility) where isolation rooms are available. The following procedures for transfer of an individual with suspected/confirmed infectious tuberculosis are utilized:

_____

_____

_____

While awaiting transfer, the individual is masked or segregated to protect employees who are without respiratory protection. (organization's name) uses the following procedures/equipment when masking and segregating an individual with suspected/confirmed infectious TB:

_____

_____

If a situation arises and the individual is not able to be transferred within 5 hours of identifying the suspected or confirmed infectious TB, the following procedures, including AFB isolation, are instituted: (list procedures used)

_____

_____

_____

Employers Who Admit and Provide Medical Services (Paragraph (c)(2)(iii))

Procedures to Isolate and Manage Care (Paragraph(c)(2)(iii)(B))

(*) The following procedures are used to isolate individuals with suspected or confirmed infectious TB.

(*) All individuals with suspected or confirmed infectious TB are placed in AFB isolation rooms or areas.

(*) _____ (organization's name) _____ uses the following procedures to minimize the time an individual with suspected or confirmed infectious TB remains outside of an AFB isolation room or area: _____ (detail responsibilities and steps)

_____

_____

(Paragraph(C)(2)(iii)(B)(1))

(*) Employee exposure in AFB isolation rooms is minimized by combining tasks the amount of time an employee spends in an AFB isolation room is minimized by _____ (list procedures used)

_____

_____ (Paragraph (c)(2)(iii)(B)(2))

(*) ____ (organization's name) _____ uses the following procedures, minimizing the number of workers entering AFB isolation rooms:

_____

_____

(*) ____ (organization's name) _____ utilizes the following procedures to delay

transport or relocation within the facility until the individual is considered non-infectious:

_____

_____

_____

(Paragraph (c)(2)(iii)(B)(3))

(*) Services are provided in the patient's room whenever feasible such as portable x-ray and _____ (list other services provided in the patient's room to minimize exposure)

_____

_____

_____

(*) This facility uses _____ (list the type of engineering controls in use—properly fitted masks or valveless respirators for the for the patient to be masked or portable containment devices)

_____

on individuals with suspected or confirmed infectious TB when it is necessary to transport or relocate the individual.

(Paragraph (c)(2)(iii)(B)(4))

(*) The following procedures assure that the individual is returned to the AFB isolation room as soon as practical after completion of the procedure _____ (list of procedures)

_____

_____

_____

(*) Services that cannot be rendered in the patient's room are provided in and area that meets the requirements for an AFB isolation room.

(*) Elective high-hazard procedures and surgery are delayed until the patient is non-infectious.(Paragraph(c)(2)(iii)(B)(5))

(*) HIGH-HAZARD PROCEDURES (Paragraph(c)(2)(iii)(C))

(*) High-hazard procedures (where TB may be aerosolized) require special precautions to prevent/minimize occupational exposure to infectious TB. The following high-hazard procedures are performed at this facility: _____ (list procedures)

_____

_____

_____

(*) Engineering Controls Maintenance Schedules and Records (Paragraph (c)(2)(iii)(D))

(*) The maintenance schedule for engineering controls is as follows:

(*) Daily—Negative pressure areas are qualitatively demonstrated by using smoke trails.

(*) Whenever HEPA filters are changed, the system is inspected and its performance monitored in accordance with current USPHS guidelines. HEPA filters are changed every _____ in this facility or whenever

_____

_____

_____

(*) Every six months—HEPA filters in contained air exhaust systems are inspected, maintained and performance monitored in accordance with current USPHS guidelines.

Clinical and/or Research Laboratories (Paragraph (c)(2)(iv))

The _____ (type of laboratory—clinical or research) _____ operates at biosafety level _____ as determined by _____ (name of laboratory director) _____ for _____ (organization's name) _____. This is in accordance with CDC/NIOSH Biosafety in Microbiological and Biomedical Laboratories).

The following controls are in operation in the laboratory at this facility _____ (list controlled access, anterooms, sealed windows and other controls required in the standard and determined necessary by the laboratory director)

_____

_____

(c)(2)(v) HOME HEALTH CARE OR HOME-BASED HOSPICE

See the following sections of this sample ECP for information regarding the ECP requirements:

(1) (c)(2)(ii) & (iii)(A) for sample statements regarding the Prompt identification of individuals with suspected or confirmed infectious TB.

(2) (c)(2)(iii) for sample statements re: procedures for minimizing employee exposure.

(3) (c)(2)(iii)(C) for a sample statement regarding high hazard procedures.

The procedures in this Exposure Control Plan minimize the occupational exposure to TB. The procedures for isolating and managing care are used until the individual with suspected or confirmed infectious TB is determined to be non-infectious or until the diagnosis for TB is ruled out.

Evaluation

Early Detection of Tuberculosis

This questionnaire gives guidance in identifying individuals who meet OSHA's definition of ''suspected infectious tuberculosis'' so that appropriate controls can be initiated.

The questionnaire has two parts: (1) reviewing the individual's TB history and (2) assessing current symptoms.

INSTRUCTIONS:

- Record each answer with a check mark
- Add your comments as the evaluator at the bottom of the page.
- Institute the facility's exposure control measures outlined in the facility's Exposure Control Plan, Respiratory Protection and Medical Surveillance Program and refer the individual for further evaluation if the individual has:

(1) A persistent cough lasting 3 or more weeks and two or more symptoms of active TB.

(2) Had a positive TB test on mucous that he/she coughed up.

(3) Been told that he/she had TB and was treated, but never finished the medication.

TB HISTORY
(Part One)

Have you ever had a positive TB skin test?
Yes No Don't Know

Have you ever had an abnormal chest x-ray?
Yes No Don't Know
If yes, how long ago?

Have you recently had the mucous you cough up tested for TB?
Yes No Don't Know
If yes, were you told it was positive
Yes No Don't Know

Have you ever been told you have Infectious Tuberculous?
Yes No Don't Know
If yes, how long ago?

Have you ever been treated with medication for Infectious TB?
Yes No Don't Know
If yes, how many medications?
One Two Over Two
Are you still taking TB medicine?
Yes No
Did you take all the TB medicine until the health care professional told you that you were finished?
Yes No

Do you live with or have you been in close contact with someone who was recently diagnosed with TB? (e.g. shelter roommate, close friend, relative)
Yes No Don't Know

CURRENT SYMPTOMS
(Part Two)

Do you have a cough that has lasted longer than three weeks?
Yes No

Do you cough up blood or mucous?
Yes No

Have you lost your appetite? Aren't hungry?
Yes No

Have you lost weight (more than 10 pounds) in the last two months? without trying to?
Yes No

Do you have night sweats (need to change the sheets or your clothes because they are wet)?
Yes No

Evaluator Comments:

_____

_____

_____

Exposure Control Methods Implemented?
Yes No

Referred for Further Evaluation? Yes No

_____

Evaluator's Signature

_____

Date

Appendix G to § 1910.1035—Smoke-trail Testing Method for Negative Pressure Isolation Rooms or Areas

A. Test Method Description

The purpose of a negative pressure AFB isolation room or area is to prevent TB droplet nuclei from escaping the isolation room or area and entering adjacent or surrounding spaces (e.g., a corridor). One method to check for negative room pressure is to use smoke-trails to demonstrate that the pressure differential is inducing airflow from the corridor through the crack at the bottom of the door (undercut) and into the isolation room or area. When performing a smoke-trail test, follow these recommendations where applicable:

1. Test only with the isolation room or area door shut. If not equipped with an anteroom, it is assumed that there will be a loss of space pressure control when the isolation or area door is opened and closed. It is not necessary to demonstrate direction of airflow when the door is open.

2. If there is an anteroom, release smoke at the inner door undercut, with both anteroom doors shut.

3. In addition to a pedestrian entry, some isolation rooms or areas are also accessed through a wider wheeled-bed stretcher door. Release smoke at all door entrances to isolation rooms or areas.

4. So that the individual conducting the test does not advertently force the smoke into the isolation room or area, hold the smoke bottle/tube parallel to the door so the smoke is released perpendicular to the direction of airflow through the door undercut.

5. Position the smoke bottle/tube tight to the floor, centered in the middle of the door jamb and approximately two inches out in front of the door.

6. Release a puff of smoke and observe the resulting direction of airflow. Repeat the test at least once or until consistent results are obtained.

7. Minimize momentum imparted to the smoke by squeezing the bulb or bottle slowly. This will also help minimize the volume of smoke released.

8. Depending on the velocity of the air through the door undercut, the smoke plume will stay disorganized or it will form a distinct streamline. In either case, the smoke will directionally behave in one of three ways. It will:

(a) Go through the door undercut into the isolation room or area,

(b) Remain motionless, or

(c) Be blown back into the corridor.

Negative pressure requires that the smoke be drawn into the isolation room or area through the door undercut.

9. Release smoke from the corridor side of the door only for occupied AFB isolation rooms or areas. If the room is unoccupied, also release smoke inside the isolation room or area (same position as in Step No. 5) to verify that released smoke remains contained in the isolation room or area (i.e., the smoke serves as a surrogate for TB droplet nuclei).

10. To assist in observing the smoke when photography or videotaping is performed, it is recommended that a dark surface be placed on the floor to maximize the contrast. Be aware that most autofocusing cameras cannot focus on smoke.

B. Testing ''As Used'' Conditions

Testing of negative pressure AFB isolation rooms or areas requires that the test reflect as-used conditions. As-used means that the isolation room or area shall remain the same during testing conditions as it is when in use for isolation. Consider the following use variables that may affect space pressurization and the performance of the negative pressure AFB isolation room or area:

1. Patient toilet rooms are mechanically exhausted to control odors. The position of the toilet room door may affect the pressure differential between the isolation room or area and the corridor. Smoke-trail tests should be performed both with the toilet room door open and the toilet room door closed. This will not be necessary if the toilet room door is normally closed and controlled to that position by a mechanical door closer.

2. An open window will adversely affect the performance of a negative pressure AFB isolation room or area. If the isolation room or area is equipped with an operable window, perform smoke-trail tests with the window open and the window closed.

3. There may be corridor doors that isolate the respiratory ward or wing from the rest of the facility. These corridor doors are provided in the initial design to facilitate space pressurization schemes and/or building life safety codes. Leaving the corridor doors open to the rest of the facility may cause pressure changes in the corridor (e.g., proximity to an elevator lobby) and affect the performance of the negative pressure AFB isolation room or area. Perform isolation room or area smoke-trail testing with these corridor doors in their ''as-used'' position, which is either normally open or normally closed.

4. Isolation rooms or areas may be equipped with auxiliary, fan-powered, recirculating, stand alone HEPA filtration or UV units. These units must be running when smoke-trail tests are performed.

5. Do not restrict corridor foot traffic while performing smoke-trail tests.

6. Negative pressure is accomplished by exhausting more air than is supplied to the isolation room or area. Some HVAC systems employ variable air volume (VAV) supply air and sometimes VAV exhaust air. By varying the supply air delivered to the space to satisfy thermal requirements, these VAV systems can adversely impact the performance of a negative pressure isolation room. If the isolation room or area or the corridor is served by a VAV system, the smoke test should be performed twice. Perform the smoke test with the thermostat set at the desired temperature and again with the thermostat set at a lower or higher temperature, depending upon the season, thus simulating the full volumetric flowrate range of the VAV system serving the area being tested.

C. Smoke

Most smoke tubes, bottles and sticks use titanium chloride ($TiCl_4$) to produce a visible fume. There is no OSHA PEL or ACGIH TLV for this chemical, although it is a recognized inhalation irritant. Health care professionals may be concerned about releasing $TiCl_4$ around pulmonary patients. The smoke released at the door undercut makes only one pass through the isolation room and is exhausted directly outside. (Isolation room air is typically not ''recirculated.'')

The CDC in the supplementary information to the 1994 TB Guidelines has indicated that ''The concern over the use of smoke is unfounded.''(Ex. 4B) Controlled tests by NIOSH have shown that the quantity of smoke released during the test is so minute that it is not measurable in the air. Nonirritating smoke tubes are available and may be utilized.

[FR Doc. 97–27020 Filed 10–16–97; 8:45 am]

BILLING CODE 4510–26–P

Friday
October 17, 1997

Part III

Department of Agriculture

Agricultural Marketing Service

7 CFR Part 1214

Kiwifruit Research, Promotion, Consumer Information Order and Referendum Procedures; Final Rule and Proposed Rule

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 1214

[FV–96–708FR]

Kiwifruit Research, Promotion, and Consumer Information Order; Referendum Procedures

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This rule provides procedures which the Department of Agriculture (Department) will use in conducting the referendum to determine whether the issuance of the proposed Kiwifruit Research, Promotion, and Consumer Information Order (Order) is approved by a majority of the producers and importers voting in the referendum and that the producers and importers favoring approval produce and import 50 percent of the total volume of kiwifruit produced and imported by persons voting in the referendum.

EFFECTIVE DATE: This rule is effective November 17, 1997.

FOR FURTHER INFORMATION CONTACT: Sonia N. Jimenez, Research and Promotion Branch, Fruit and Vegetable Division, AMS, USDA, P.O. Box 96456, Room 2535–S, Washington, DC 20090–6456, telephone (202) 720–9916 or (888) 720–9917.

SUPPLEMENTARY INFORMATION: This rule is issued under the Kiwifruit Research, Promotion, and Consumer Information Act [7 U.S.C. 7461-7473], hereinafter referred to as the Act.

This rule provides the procedures under which the referendum will be conducted.

Executive Order 12988

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. It is not intended to have retroactive effect. This rule will not preempt any State or local laws, regulations, or policies, unless they present an irreconcilable conflict with this rule.

The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 558 of the Act [7 U.S.C. 7467], after an Order is implemented, a person subject to the Order may file a petition with the Secretary stating that the Order or any provision of the Order, or any obligation imposed in connection with the Order, is not in accordance with law and requesting a modification of the Order or an exemption from the Order. The petitioner is afforded the opportunity for a hearing on the petition. After such hearing, the Secretary will make a ruling on the petition. The Act provides that the district courts of the United States in any district in which a person who is a petitioner resides or carries on business are vested with jurisdiction to review the Secretary's ruling on the petition, if a complaint for that purpose is filed within 20 days after the date of the entry of the ruling.

Executive Order 12866 and Regulatory Flexibility Act

This rule has been determined not significant for purposes of Executive Order 12866, and therefore has not been reviewed by the Office of Management and Budget.

In accordance with the Regulatory Flexibility Act [5 U.S.C. 601 *et seq.*], the Agency has examined the impact of this rule on small entities. Accordingly, we have performed this Final Regulatory Flexibility Analysis.

Legislation to create a generic program of promotion and research for kiwifruit became effective on April 4, 1996.

Section 561 of the Act [7 U.S.C. 7470] provides that the Secretary of Agriculture (Secretary) shall conduct a referendum during the 60-day period immediately preceding the proposed effective date of an Order to determine whether the issuance of an Order is favored by a majority of the producers and importers voting in the referendum. Paragraph (a)(2) of Section 561 of the Act [7 U.S.C. 7470] requires that the Order be approved by a majority of producers and importers voting in the referendum and that the producers and importers favoring approval produce and import 50 percent or more of the volume of kiwifruit produced and imported by persons voting in the referendum.

There are approximately 650 producers, 45 importers, and 65 handlers of kiwifruit that would be covered by the program. Small agricultural service firms, which will include the handlers and importers who would be covered under the Order, have been defined by the Small Business Administration (SBA) [13 CFR 121.601] as those whose annual receipts are less than $5 million and small agricultural producers, those who would be required to pay assessments, as those having annual receipts of $500,000. Only one handler has been identified to have $5 million or more in annual sales. In addition, there are 10 producers at or over the $500,000 annual sales receipts threshold. The Department does not have specific information regarding the size of importers. However, it could be concluded that the majority of kiwifruit producers and importers may be classified as small entities.

The Department is aware of kiwifruit producers in California, Oregon, Pennsylvania, South Carolina, and importers that import kiwifruit from Chile, New Zealand, and Italy. The Department believes that these individuals would include a majority of the producers and importers that would be covered under the program. The Department is also aware that some individuals may be producers of ''hardy kiwifruit,'' a different species of kiwifruit, known as *Actinidia arguta,* which would not be covered under the proposed program. However, the Department does not have specific information regarding how many individuals produce only the ''hardy kiwifruit'' versus the ''fuzzy'' most common kiwifruit species, known as *Actinidia deliciosa.* Therefore, the total number of producers believed to be covered by the program is the same as in the proposed rule on this action.

Other names for the species *Actinidia arguta* (hardy kiwifruit) are baby kiwifruit, kiwifruit grape, and kiwiberry. There are no official statistics on this commodity because it is such a small and new crop. According to comments received on the Order published on October 2, 1996, in the **Federal Register**, this species is grown in California, Oregon, Pennsylvania, Washington, Virginia, and British Columbia. The production in Virginia and Pennsylvania is not commercially marketed. Oregon production on 5 acres was a total of 216,000 pounds over the last 3 years. It takes 3 to 5 years to harvest the first crop. The hardy kiwifruit is hand-harvested and packed in 6-ounce berry baskets like raspberries. The harvesting, storage, handling, consumer recognition, and marketing of this species is completely different from the most common fuzzy kiwifruit or *Actinidia deliciosa.* Accordingly, we changed the definition of kiwifruit in the proposed order to mean all varieties of fresh kiwifruit classified under the species *Actinidia deliciosa* or the genus *Actinidia.* That definition of kiwifruit is added in this rule as well. All references to ''kiwifruit'' in this document, therefore, mean the *Actinidia deliciosa* species.

California is the source for practically all (99.7 percent) of the kiwifruit produced in the United States. The California kiwifruit industry consists of approximately 600 producers and 65 handlers. Production rose by 75 percent between 1984 and 1996, increasing from

18 thousand tons to 31.5 tons. In the period from 1984 through 1996, the value of production fell by 26 percent.

Most U.S. kiwifruit is utilized fresh. Fresh utilization increased by 123 percent between 1984 and 1996, growing from 11.7 thousand tons to 26.1 thousand tons. The season average price during 1984 through 1996 fell by 53 percent, declining from $1,070 per ton to $502 per ton. Exports accounted for about 30 percent of U.S. fresh utilization during that period.

Between 1992 and 1996, the average annual production per producer, including kiwifruit for processing, was 99 tons or 28,286 7-pound trays of kiwifruit. The average price was $406 per ton, giving an average return of about $40,000 per producer per year. A typical tray price during this period was $1.42 per tray, and the average amount shipped per handler was about 148,276 trays, yielding an average annual revenue per handler of $210,552. U.S. importers handled an average of 184,857 trays per year per importer. During this period, the average value of total imports per year was $18.3 million (f.o.b. country of origin). The majority of kiwifruit came from Chile, with the remaining coming from New Zealand and Italy. In 1996, imports totaled 87.9 million pounds, up 5 percent from 1995. The value of imports in 1996 was $26.5 million.

The proposed rule published in the **Federal Register** on October 2, 1996, provided statistics on production, value of production, fresh utilization, average price, average return per producer, average annual revenue per handler, and other related statistics that are different from the statistics provided in this rule. These changes are due to the fact that the October 2, 1996, rule relied on statistics from 1985 through 1995 because 1996 crop year statistics were not available. When 1996 statistics are added to the averages, the final averages change because the domestic 1996 crop statistics are considerably lower in terms of production, and fresh utilization. For example, production from 1985 to 1995 increased an average of 119 percent. However, when adding 1996 production, the average from 1985 to 1996 shows an average increase of only 75 percent. Therefore, adding the 1996 statistics to the averages provided in the October 2 proposed rule changes the statistical averages, in some cases considerably, making the statistics for production and fresh utilization lower than previously indicated.

This rule provides the procedures under which kiwifruit producers and importers may vote on whether they want the kiwifruit research and promotion program to be implemented. Kiwifruit producers of 500 pounds or more and importers of 10,000 pounds or more annually can vote in the referendum. There are approximately 700 eligible voters.

The Department will keep all these individuals informed throughout the program implementation and referendum process to ensure that they are aware of and are able to participate in the program implementation process. In addition, trade associations and related industry media will receive news releases and other information regarding the implementation and referendum process.

There is a federal marketing order program and a California state program for kiwifruit. The marketing order regulations for grade, size, maturity, and containers are designed to assure consumers of consistently good quality California kiwifruit. The marketing order and its regulations allow small farmers to compete effectively in an increasingly competitive marketplace. The California Kiwifruit Commission (CKC) administers the California state program for kiwifruit. The CKC is composed of kiwifruit producers, packers, and handlers.

In 1996–97 it is estimated that producers would pay $1.15 million in assessments at a rate of 17 cents per kiwifruit tray or tray equivalent. Handlers collect the assessments and remit the money to the CKC.

Voting in the referendum is optional. However, if producers and importers choose to vote, the burden of voting will be offset by the benefits of having the opportunity to vote on whether they want the program or not.

The Department considered requiring eligible voters to vote in person at various Department offices across the country. However, conducting the referendum from one central location by mail ballot is more cost effective for this program. Also, the Department will provide easy access to information for potential voters through a toll free telephone line.

Paperwork Reduction Act

In accordance with the Office of Management and Budget (OMB) regulations [5 CFR Part 1320] which implements the Paperwork Reduction Act of 1995 [44 U.S.C. Chapter 35], the referendum ballot has been approved by the Office of Management and Budget (OMB) and has been assigned OMB number 0581–0093.

Title: National Research, Promotion, and Consumer Information Programs.

OMB Number: 0581–0093.

Expiration Date of Approval: October 31, 1997.

Type of Request: Revision of a currently approved information collection for research and promotion programs.

Abstract: The information collection requirements in this request are essential to carry out the intent of the Act.

The burden associated with the ballot is as follows:

Estimate of Burden: Public reporting burden for this collection of information is estimated to average .25 hours per response for each producer and importer.

Respondents: Producers and importers.

Estimated Number of Respondents: 700.

Estimated Number of Responses per Respondent: 1 every 6 years (.16).

Estimated Total Annual Burden on Respondents: 29 hours.

No comments were received concerning the collection of information, the accuracy of the estimated burden, or ways to enhance or minimize the collection of information.

Background

The Act authorizes the Secretary to establish a national kiwifruit research, promotion, and consumer information program. The program would be funded by an assessment levied on producers and importers not to exceed 10 cents per 7-pound tray of kiwifruit. Producers who produce less than 500 pounds annually, importers who import less than 10,000 pounds annually, and kiwifruit sold directly to a consumer by a producer for a purpose other than resale and domestic and imported kiwifruit for processing are exempt from assessments.

Assessments would be used to pay for: research, promotion, and consumer information; administration, maintenance, and functioning of the Board; and expenses incurred by the Secretary in implementing and administering the Order, including referendum costs.

Section 561 of the Act [7 CFR part 7470] requires that a referendum be conducted among eligible producers and importers of kiwifruit to determine whether they favor implementation of the Order. The Order shall become effective if it is approved by a majority of producers and importers voting in the referendum and the producers and importers favoring approval produce and import more than 50 percent of the total volume of kiwifruit produced and imported by persons voting in the referendum.

A proposed rule containing the proposed Order was published in the October 2, 1996, issue of the **Federal Register** [61 FR 51378]. A proposal containing that proposed order that will be subject to referendum is being published separately in this issue of the **Federal Register**.

This final rule provides the procedures under which kiwifruit producers and importers may vote on whether they want the kiwifruit research and promotion program to be implemented. Kiwifruit producers of 500 pounds or more and importers of 10,000 pounds or more annually can vote in the referendum. There are approximately 700 eligible voters.

This final rule will add a new subpart which establishes procedures to be used in the referendum. This subpart covers definitions, voting, instructions, use of subagents, ballots, the referendum report, and confidentiality of information.

A proposed rule with a request for comments on the referendum procedures was published in the October 2, 1996, issue of the **Federal Register** [61 FR 51391]. No comments were received on the proposal.

However, comments were received on the proposed Order regarding the definition of kiwifruit. The commenters expressed that some individuals may be producers of ''hardy kiwifruit,'' a different species of kiwifruit, known as *Actinidia arguta.* Other names for this species (hardy kiwifruit) are baby kiwifruit, kiwifruit grape, and kiwiberry. There are no official statistics on this commodity because it is such a small and new crop. According to comments received on the proposed Order this species is grown in California, Oregon, Pennsylvania, Washington, Virginia, and British Columbia. The production in Virginia and Pennsylvania is not commercially marketed. Oregon production on 5 acres was a total of 216,000 pounds over the last 3 years. It takes 3 to 5 years to harvest the first crop. The hardy kiwifruit is hand-harvested and packed in 6-ounce berry baskets like raspberries. The harvesting, storage, handling, consumer recognition, and marketing of this species is completely different from the most common fuzzy kiwifruit or *Actinidia deliciosa.* Accordingly, we changed the definition of kiwifruit in the proposed order to mean all varieties of fresh kiwifruit classified under the species *Actinidia deliciosa* or the genus *Actinidia.* That definition of kiwifruit is added in this rule as well. All references to ''kiwifruit'' in this document, therefore, mean the *Actinidia deliciosa* species.

Accordingly, no changes to the text of the regulation as proposed are made in this final rule, except for the addition of the definition of kiwifruit that appears in the proposed order. After consideration of all relevant material presented, it is found that this final rule effectuates the declared policy of the Act.

List of Subjects in 7 CFR Part 1214

Administrative practice and procedure, Advertising, Consumer information, Marketing agreements, Kiwifruit, Promotion, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, Title 7, chapter XI of the Code of Federal Regulations is amended as follows:

1. Part 1214 is added to read as follows:

PART 1214—KIWIFRUIT RESEARCH, PROMOTION, AND CONSUMER INFORMATION ORDER

Subpart A—Reserved

Subpart B—Reserved

Subpart C—Procedure for the Conduct of Referenda in Connection With the Kiwifruit Research, Promotion, and Consumer Information Order

Sec.

Authority: 7 U.S.C. 7461–7473.

Subpart C—Procedure for the Conduct of Referenda in Connection With the Kiwifruit Research, Promotion, and Consumer Information Order

§ 1214.200 General.

A referendum to determine whether eligible producers and importers favor the issuance of a proposed Kiwifruit Research, Promotion, and Consumer Information Order shall be conducted in accordance with this subpart.

§ 1214.201 Definitions.

Unless otherwise defined in this section, the definition of terms used in this subpart shall have the same meaning as the definitions in the Order.

(a) *Administrator* means the Administrator of the Agricultural Marketing Service, with power to redelegate, or any officer or employee of the Department to whom authority has been delegated or may hereafter be delegated to act in the Administrator's stead.

(b) *Order* means the Kiwifruit Research, Promotion, and Consumer Information Order.

(c) *Referendum agent* or agent means the individual or individuals designated by the Secretary to conduct the referendum.

(d) *Representative period* means the period designated by the Secretary.

(e) *Person* means any individual, group of individuals, partnership, corporation, association, cooperative, or any other legal entity. For the purpose of this definition, the term ''partnership'' includes, but is not limited to:

(1) A husband and wife who has title to, or leasehold interest in, kiwifruit production facilities and equipment as tenants in common, joint tenants, tenants by the entirety, or, under community property laws, as community property, and

(2) So-called ''joint ventures,'' wherein one or more parties to the agreement, informal or otherwise, contributed capital and others contributed labor, management, equipment, or other services, or any variation of such contributions by two or more parties so that it results in the production or importation of kiwifruit and the authority to transfer title to the kiwifruit so produced or imported.

(f) *Eligible producer* means any person or entity defined as a producer who produced 500 pounds or more of kiwifruit during the representative period and who:

(1) Owns or shares in the ownership of kiwifruit production facilities and equipment resulting in the ownership of the kiwifruit produced;

(2) Rents kiwifruit production facilities and equipment resulting in the ownership of all or a portion of the kiwifruit produced;

(3) Owns kiwifruit production facilities and equipment but does not manage them and, as compensation, obtains the ownership of a portion of the kiwifruit produced; or

(4) Is a party in a landlord-tenant relationship or a divided ownership arrangement involving totally independent entities cooperating only to produce kiwifruit who share the risk of loss and receive a share of the kiwifruit produced. No other acquisition of legal title to kiwifruit shall be deemed to result in persons becoming eligible producers.

(g) *Eligible importer* means any person or entity defined as an importer who imported 10,000 pounds or more during the representative period. Importation occurs when commodities originating outside the United States are entered or withdrawn from the U.S. Customs

Service for consumption in the United States. Included are persons who hold title to foreign-produced kiwifruit immediately upon release by the U.S. Customs Service, as well as any persons who act on behalf of others, as agents or broker, to secure the release of kiwifruit from the U.S. Customs Service when such kiwifruit are entered or withdrawn for consumption in the United States.

(h) *Kiwifruit* means all varieties of fresh kiwifruit classified under the species *Actinidia deliciosa* or the genus *Actinidia,* whose fruit is a large berry, oval in shape, with a brown skin covered in hairs, which are grown in or imported into the United States.

§ 1214.202 Voting.

(a) Each person who is an eligible producer or importer, as defined in this subpart, at the time of the referendum and during the representative period, shall be entitled to cast only one ballot in the referendum. However, each producer in a landlord-tenant relationship or a divided ownership arrangement involving totally independent entities cooperating only to produce kiwifruit, in which more than one of the parties is a producer, shall be entitled to cast one ballot in the referendum covering only such producer's share of the ownership.

(b) Proxy voting is not authorized, but an officer or employee of an eligible corporate producer or importer, or an administrator, executor, or trustee of an eligible producing or importing entity may cast a ballot on behalf of such producer or importer entity. Any individual so voting in a referendum shall certify that such individual is an officer or employee of the eligible producer or importer, or an administrator, executor, or trustee of an eligible producing or importing entity, and that such individual has the authority to take such action. Upon request of the referendum agent, the individual shall submit adequate evidence of such authority.

(c) All ballots are to be cast by mail.

§ 1214.203 Instructions.

The referendum agent shall conduct the referendum, in the manner provided in this subpart, under the supervision of the Administrator. The Administrator may prescribe additional instructions, not inconsistent with the provisions of this section, to govern the procedure to be followed by the referendum agent. Such agent shall:

(a) Determine the time of commencement and termination of the period during which ballots may be cast.

(b) Provide ballots and related material to be used in the referendum. Ballot material shall provide for recording essential information including that needed for ascertaining:

(1) Whether the person voting, or on whose behalf the vote is cast, is an eligible voter;

(2) The total volume of kiwifruit produced by the voting producer during the representative period; and

(3) The total volume of kiwifruit imported by the voting importer during the representative period.

(c) Give reasonable advance public notice of the referendum:

(1) By utilizing available media or public information sources, without incurring advertising expense, to publicize the dates, places, method of voting, eligibility requirements, and other pertinent information. Such sources of publicity may include, but are not limited to, print and radio; and

(2) By such other means as the agent may deem advisable.

(d) Mail to eligible producers and importers, whose names and addresses are known to the referendum agent, the instructions on voting, a ballot, and a summary of the terms and conditions of the proposed Order. No person who claims to be eligible to vote shall be refused a ballot.

(e) At the end of the voting period, collect, open, number, and review the ballots and tabulate the results in presence of an agent of the Office of Inspector General.

(f) Prepare a report on the referendum.

(g) Announce the results to the public.

§ 1214.204 Subagents.

The referendum agent may appoint any individual or individuals deemed necessary or desirable to assist the agent in performing such agent's functions in this subpart. Each individual so appointed may be authorized by the agent to perform any or all of the functions which, in the absence of such appointment, shall be performed by the agent.

§ 1214.205 Ballots.

The referendum agent and subagents shall accept all ballots cast; but, should they, or any of them, deem that a ballot should be challenged for any reason, the agent or subagent shall endorse above their signature, on the ballot, a statement to the effect that such ballot was challenged, by whom challenged, the reasons therefore, the results of any investigations made with respect thereto, and the disposition thereof. Ballots invalid under this subpart shall not be counted.

§ 1214.206 Referendum report.

Except as otherwise directed, the referendum agent shall prepare and submit to the Administrator a report on results of the referendum, the manner in which it was conducted, the extent and kind of public notice given, and other information pertinent to analysis of the referendum and its results.

§ 1214.207 Confidential information.

The ballots and other information or reports that reveal, or tend to reveal, the vote of any person covered under the Act and the voting list shall be held confidential and shall not be disclosed.

Dated: October 8, 1997.

Robert C. Keeney,

Deputy Administrator, Fruit and Vegetable Programs.

[FR Doc. 97–27323 Filed 10–16–97; 8:45 am]

BILLING CODE 3410–02–U

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 1214

[FV–96–705–PR2]

Proposed Kiwifruit Research, Promotion, and Consumer Information Order

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule.

SUMMARY: This proposed rule would establish an industry-funded research, promotion, and consumer information program for fresh kiwifruit. Under the proposed Kiwifruit Research, Promotion, and Consumer Information Order (Order), producers and importers would pay an assessment not to exceed 10 cents per 7-pound tray of kiwifruit to the proposed National Kiwifruit Board (Board). Composed of producers and importers or exporters, the Board would use the assessments collected to conduct a generic program of research, promotion, and consumer information to maintain, expand, and develop markets for kiwifruit.

DATES: A referendum order establishing the voting period for the referendum and the representative period for voter eligibility will be published at a later date in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Sonia N. Jimenez, Research and Promotion Branch, Fruit and Vegetable Division, AMS, USDA, STOP Code 0244, 1400 Independence Ave, SW, Washington, DC 20250–0244, fax (202) 205–2800, telephone (202) 720–9916 or (1)(888) 720–9917.

SUPPLEMENTARY INFORMATION: This proposed Order is issued under the National Kiwifruit Research, Promotion, and Consumer Information Act, Subtitle V of the Federal Agricultural Improvement and Reform Act of 1996 [Pub. L. 104–127], enacted April 4, 1996, hereinafter referred to as the Act.

Executive Order 12988

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. It is not intended to have retroactive effect. This rule would not preempt any State or local laws, regulations, or policies, unless they present an irreconcilable conflict with this rule.

The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 558 of the Act [7 U.S.C. 7467], after an Order is implemented, a person subject to the Order may file a petition with the Secretary stating that the Order or any provision of the Order, or any obligation imposed in connection with the Order, is not in accordance with law and requesting a modification of the Order or an exemption from the Order. The petitioner is afforded the opportunity for a hearing on the petition. After such hearing, the Secretary will make a ruling on the petition. The Act provides that the district courts of the United States in any district in which a person who is a petitioner resides or carries on business are vested with jurisdiction to review the Secretary's ruling on the petition, if a complaint for that purpose is filed within 20 days after the date of the entry of the ruling.

Executive Order 12866 and Regulatory Flexibility Act

This rule has been determined not significant for purposes of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget.

In accordance with the Regulatory Flexibility Act [5 U.S.C. 601 *et seq.*], the Agency has examined the impact of the proposed rule on small entities.

The kiwifruit industry initiated this program by asking the U.S. Congress (Congress) to pass legislation to create a generic program of promotion and research for kiwifruit. Congress found that this program is vital to the welfare of kiwifruit producers and other persons concerned with producing, marketing, and processing kiwifruit.

This program is intended to: develop and finance an effective and coordinated program of research, promotion, and consumer information regarding kiwifruit; strengthen the position of the kiwifruit industry in domestic and foreign markets and maintain, develop, and expand markets for kiwifruit; and to treat domestically produced kiwifruit and imported kiwifruit equitably.

The industry support for the program will be determined during the referendum to be conducted by the Department. Dates for the referendum will be announced by the Secretary no later than 60 days before the referendum.

This program was initiated by industry, industry must approve the program in a referendum in advance of its implementation, and industry members would serve on the promotion board that would administer the program under the Department's supervision. In addition, any person subject to the program may file with the Secretary a petition stating that the order or any provision is not in accordance with law and requesting a modification of the order or an exemption from the order. Administrative proceedings were discussed earlier in this proposed rule.

In this program, handlers would be required to collect assessments from producers, file reports, and submit assessments to the promotion board. Importers would be required to remit to the promotion board assessments not collected by the U.S. Customs Service (Customs) and to file reports with the promotion board. In addition, exempt producers and importers would be required to file an exemption application. While the proposed Order would impose certain recordkeeping requirements on handlers and importers, information required under the proposed Order could be compiled from records currently maintained. The forms require the minimum information necessary to effectively carry out the requirements of the program, and their use is necessary to fulfill the intent of the Act. The estimated cost in providing information to the promotion board by the 760 respondents would be $7,842.50 or $10.32 per respondent per year.

The Department would oversee program operations and, if the program is implemented, every 6 years would conduct a referendum to determine whether the kiwifruit industry supports continuation of the program.

There are approximately 650 producers, 45 importers, and 65 handlers of kiwifruit that would be covered by the program. Small agricultural service firms, which would include the handlers and importers who would be covered under the Order, have been defined by the Small Business Administration (SBA) [13 CFR 121.601] as those whose annual receipts are less than $5 million and small agricultural producers, those who would be required to pay assessments, as those having annual receipts of $500,000. Only one handler has been identified to have $5 million or more in annual sales. In addition, there are 10 producers at or over the $500,000 annual sales receipts threshold. Accordingly, the majority of handlers and producers may be classified as small entities. While the Department does not have specific information regarding the size of importers, it may be concluded that the majority of importers may be classified as small entities.

The Department is aware of producers in California, Oregon, Pennsylvania, and South Carolina, and importers that import kiwifruit from Chile, New Zealand, and Italy. The Department believes that these individuals would include a majority of the producers and

importers that would be covered under the program. The Department is also aware that some individuals may be producers of ''hardy kiwifruit,'' a different species of kiwifruit, known as *Actinidia arguta,* which would not be covered under the proposed program. However, the Department does not have specific information regarding how many individuals produce only the ''hardy kiwi'' versus the ''fuzzy'' most common kiwifruit species, known as *Actinidia deliciosa*. Therefore, the total number of producers believed to be covered by the program is the same as in the first proposed rule.

Other names for the species *Actinidia arguta* (hardy kiwifruit) are baby kiwifruit, kiwifruit grape, and kiwiberry. There are no official statistics on this commodity because it is such a small and new crop. According to comments received, this species is grown in California, Oregon, Pennsylvania, Washington, Virginia, and British Columbia. The production in Virginia and Pennsylvania is not commercially marketed. Oregon production on 5 acres was a total of 216,000 pounds over the last 3 years. It takes 3 to 5 years to harvest the first crop. The hardy kiwifruit is hand-harvested and packed in 6-ounce berry baskets like raspberries. The harvesting, storage, handling, consumer recognition, and marketing of this species is completely different from the most common fuzzy kiwifruit or *Actinidia deliciosa*. All references to ''kiwifruit'' in this document, therefore, mean the *Actinidia deliciosa* species.

California is the source for practically all (99.7%) of the kiwifruit produced in the United States. The California kiwifruit industry consists of approximately 600 producers and 65 handlers. Production rose by 75 percent between 1984 and 1996, increasing from 18 thousand tons to 31.5 thousand tons. In the period from 1984 through 1996, the value of production fell by 26 percent.

Most U.S. kiwifruit is utilized fresh. Fresh utilization increased by 123 percent between 1984 and 1996, growing from 11.7 thousand tons to 26.1 thousand tons. The season average price during 1984 through 1996 fell by 53 percent, declining from $1,070 per ton to $502 per ton. Exports accounted for about 30 percent of U.S. fresh utilization during that period.

Between 1992 and 1996, the average annual production per producer, including kiwifruit for processing, was 99 tons or 28,286 7-pound trays of kiwifruit. The average price was $406 per ton, giving an average return of about $40,000 per producer per year. A typical tray price during this period was $1.42 per tray, and the average amount shipped per handler was about 148,276 trays, yielding an average annual revenue per handler of $210,552. U.S. importers handled an average of 184,857 trays per year per importer. During this period, the average value of total imports per year was $18.3 million (f.o.b. country of origin). The majority of kiwifruit came from Chile, with the remaining coming from New Zealand and Italy. In 1996, imports totaled 87.9 million pounds, up 5 percent from 1995. The value of imports in 1996 was $26.5 million.

The proposed rule published in the **Federal Register** on October 2, 1996, provided statistics on production, value of production, fresh utilization, average price, average return per producer, average annual revenue per handler, and other related statistics that are different from the statistics provided in this rule. These changes are due to the fact that the October 2, 1996, rule relied on statistics from 1985 through 1995 because 1996 crop year statistics were not available. When 1996 statistics are added to the averages, the final averages change because the domestic 1996 crop statistics are considerably lower in terms of production, and fresh utilization. For example, production from 1985 to 1995 increased an average of 119 percent. However, when adding 1996 production, the average from 1985 to 1996 shows an average increase of only 75 percent. Therefore, adding the 1996 statistics to the averages provided in the October 2 proposed rule changes the statistical averages, in some cases considerably, making the statistics for production and fresh utilization lower than previously indicated.

The proposed kiwifruit Order would authorize assessment fees on producers (to be collected by first handlers) and on importers (collected by the U.S. Customs Service) of up to 10 cents per 7-pound tray. The Board, which will be composed of kiwifruit producers, importers, and, possibly, exporters, must recommend the assessment rate, which is subject to oversight by the Secretary, as are the other rules and regulations. At the maximum rate of assessment, the promotion board would collect $2.1 million to administer the program. Assessments on domestic production are expected to represent 45 percent of the income under the program.

The effect of the assessments will depend on the actual rate recommended by the Board. At the maximum rate, it is expected that the effect on producers would be approximately 8 percent of their average return. However, the Order would exempt producers of less than 500 pounds of kiwifruit a year, importers of less than 10,000 pounds a year, and kiwifruit sold for processing and sold directly to consumers. Furthermore, under the proposed program, the promotion board could authorize different reporting schedules based on different marketing practices. This could be of benefit specially to small businesses for whom a less frequent reporting period would diminish the reporting burden.

The Department would keep all of these individuals informed throughout the program implementation and referendum process to ensure that they are aware of and are able to participate in the implementation process. In addition, trade associations and related industry media would receive news releases and other information regarding the implementation and referendum process. Furthermore, all the information would be available through e-mail.

If the program is implemented, the promotion board would develop guidelines for compliance with the program.

In addition, the kiwifruit industry would nominate individuals to serve as members of the promotion board. These individuals would recommend the assessment rate, programs and projects, a budget, and any other rules and regulations that might be necessary for the administration of the program. The Department would ensure that the nominees represent the kiwifruit industry as specified in the Act.

There is a federal marketing order program for kiwifruit in California which is administered by the Kiwifruit Administrative Committee (KAC), under the Department's supervision. KAC is composed of California producers. The marketing order regulations for grade, size, maturity, and containers are designed to assure consumers of consistently good quality California kiwifruit. The marketing order and its regulations allow small farmers to compete effectively in an increasingly competitive marketplace. Under the marketing order, handlers are required to submit information pertaining to and pay assessments on kiwifruit shipments. The assessment rate recommended by the KAC is derived by dividing anticipated expenses by expected shipments of kiwifruit. Because that rate is applied to actual shipments, it must be established at a rate which will produce sufficient income to pay the KAC's expected expenses. The 1996–97 assessment rate was set at 1.75 cents per tray or tray equivalent of kiwifruit. The 1995–96 rate of assessment was 1.5 cent

per tray or tray equivalent of kiwifruit. Each handler pays an average of $2,000 per year in assessments. The estimated reporting burden per year on individual handlers is estimated at 4.2 hours or $42.00 per handler under the marketing order.

The California Kiwifruit Commission (CKC) administers a California state program for kiwifruit. The CKC is composed of kiwifruit producers, packers, and handlers. In 1995–96 producers paid $1.4 million in assessments at a rate of 17 cents per tray or tray equivalent. In 1996–97 it is estimated that producers would pay $1.15 million in assessments at a rate of 17 cents per tray or tray equivalent. Handlers collect the assessments and remit them to the CKC.

The collection of information required under the proposed order for the research and promotion program would be similar to the marketing order program. However, the KAC and the promotion board would keep their information separate to comply with confidentiality requirements under the programs. Furthermore, using the same source of information would reduce the burden on producers and handlers of all sizes.

In the past, the CKC participated in a voluntary promotional program with Chilean kiwifruit growers to jointly advertise kiwifruit in the United States. This program, however, does not provide enough resources to be as effective as a national generic program could be. In addition, other importing countries and private companies spend considerable amounts of resources in kiwifruit advertising. The purpose of this proposed program is not to restrict the individual promotions but to add a generic promotion program for kiwifruit where industry segments pull together resources for the benefit of the whole industry.

The absence of a generic program for kiwifruit may have a negative impact on the industry because other commodity groups, specifically for competing fruits, conduct promotion activities to maintain and expand their markets. The kiwifruit industry would be at a disadvantage because individual producers, handlers, and importers would not be able to implement and finance such a program without cooperative action. In addition, Agricultural Issues Forum, a group of 15 California commodity organizations, conducted a study in mid-1995 and reported in early 1996 that consumers strongly support the concept of farmers working together to promote their products, conduct product research, engage in consumer education programs, and set quality standards and inspect products. Consumers said that they benefitted from these activities and were more inclined to buy those products. Eighty-one percent of the farmers surveyed said that mandated programs were either very important or important in promoting products. The survey was conducted among farmers, public policy leaders, consumers, retailers, and allied industries.

In order to conduct the Regulatory Flexibility Analysis regarding the impact of this proposed Order on small entities, the proposed rule that was published in the **Federal Register** on October 2, 1996 [61 FR 51378] invited comments concerning the potential effects of the proposed Order. No comments were received concerning the impact of the proposed order on small entities. However, as explained earlier in this rule, ''hardy kiwifruit'' producers would not be covered under the program because the species *Actinidia arguta* is considerably different from the most common ''fuzzy kiwifruit'' species *Actinidia deliciosa*. This would have a positive impact on small businesses since most of the producers of ''hardy kiwifruit'' are considered small businesses.

In addition, it is expected that the proposed order would be very beneficial to the kiwifruit industry, especially small businesses who would not be able to afford a nationwide comprehensive program individually.

It is estimated that there are approximately 700 kiwifruit producers and importers that would be eligible to vote in the referendum. It would take an average 15 minutes for each voter to read the voting instructions and complete the referendum ballot. The total burden on the total number of voters will be 29 hours.

Paperwork Reduction Act

In accordance with the Office of Management and Budget (OMB) regulations [5 CFR Part 1320] which implement the Paperwork Reduction Act of 1995 [44 U.S.C. Chapter 35], the information collection and recordkeeping requirements that would be imposed by this proposed Order were approved by OMB on December 16, 1996.

Title: National Research, Promotion, and Consumer Information Programs.

OMB Number: 0581–0093, except for the Promotion Board nominee background statement form which is assigned OMB number 0505–0001.

Expiration Date of Approval: October 31, 1997.

Type of Request: Revision of a currently approved information collection for research and promotion programs.

Abstract: The information collection requirements in this request are essential to carry out the intent of the Act.

While the proposed Order would impose certain recordkeeping requirements on handlers and importers, information required under the proposed Order could be compiled from records currently maintained. The proposed Order's provisions have been carefully reviewed and every effort has been made to minimize any unnecessary recordkeeping costs or requirements, including efforts to utilize information already maintained by handlers under the federal marketing order program in California and the CKC. The information needed would be taken from financial reports or sales receipts already maintained.

The forms require the minimum information necessary to effectively carry out the requirements of the program, and their use is necessary to fulfill the intent of the Act. Such information can be supplied without data processing equipment or outside technical expertise. In addition, there are no additional training requirements for individuals filling out reports and remitting assessments to the promotion board. The forms would be simple, easy to understand, and place as small a burden as possible on the person required to file the information.

Collecting information monthly coincides with normal business practices. Collecting information less frequently would hinder the promotion board from effectively carrying out the provisions of its program. Requiring reports less frequently than monthly would impose additional recordkeeping requirements by requiring information from several months to be consolidated prior to filling out the form rather than just copying end-of-month figures already available onto the forms. The timing and frequency of collecting information is intended to meet the needs of the industry while minimizing the amount of work necessary to fill out the required reports. In addition, the information to be included on these forms is not available from other sources because such information relates specifically to individual producers, importers, and handlers who are subject to or exempted from the provisions of the Act. Therefore, there is no practical method for collecting the required information without the use of these forms.

The estimated cost in providing information to the promotion board by the 760 respondents would be $7,842.50

or $10.32 per respondent. This total has been estimated by multiplying 784.25 (total burden hours requested) by $10.00 per hour, a sum deemed to be reasonable should the respondents be compensated for their time.

Information collection requirements that are included in this proposal include:

(1) *A periodic report by each handler who handles kiwifruit.*

Estimate of Burden: Public reporting burden for this collection of information is estimated to average .50 hours per each handler reporting on kiwifruit handled.

Respondents: Handlers.

Estimated Number of Respondents: 65.

Estimated Number of Responses per Respondent: 12.

Estimated Total Annual Burden on Respondents: 390 hours.

(2) *A periodic report by each importer who imports kiwifruit.*

Estimate of Burden: Public reporting burden for this collection of information is estimated to average .25 hours per each importer reporting on kiwifruit imported.

Respondents: Importers.

Estimated Number of Respondents: 45.

Estimated Number of Responses per Respondent: 12.

Estimated Total Annual Burden on Respondents: 135 hours.

(3) *An exemption application for producers and importers of kiwifruit producing less than 500 pounds and importing less than 10,000 pounds of kiwifruit a year respectively, persons which sell directly to consumers or sell kiwifruit for processing who will be exempt from assessments and reporting requirements.*

Estimate of Burden: Public reporting burden for this collection of information is estimated to average .25 hours per response for each exempt producer and importer.

Respondents: Exempt producers and importers

Estimated Number of Respondents: 50.

Estimated Number of Responses per Respondent: 1.

Estimated Total Annual Burden on Respondents: 12.5 hours.

(4) *A referendum ballot to be used to determine whether producers and importers covered by the Order favor implementation or continuance of the Order.*

Estimate of Burden: Public reporting burden for this collection of information is estimated to average .25 hours per response for each producer and importer.

Respondents: Producers and importers.

Estimated Number of Respondents: 700.

Estimated Number of Responses per Respondent: 1 every 6 years (.16).

Estimated Total Annual Burden on Respondents: 29 hours.

(5) *Nominations.*

Estimate of Burden: Public reporting burden for this collection of information is estimated to average .5 hours per response.

Respondents: Producers and importers.

Estimated number of Respondents: 700.

Estimated Number of Responses per Respondent: 1 every 3 years (.33)

Estimated Total Annual Burden on Respondents: 115.5 hours.

(6) *A request for refund of assessments collected by Customs for exempt importers.*

Estimate of Burden: Public reporting burden for this collection of information is estimated to average .25 hours per response for each exempt importer requesting a refund of assessments collected by Customs.

Respondents: Exempt importers.

Estimated number of Respondents: 5

Estimated Number of Responses per Respondent: 1

Estimated Total Annual Burden on Respondents: 1.25 hours.

(7) *A background questionnaire for nominees.*

Estimate of Burden: Public reporting burden for this collection of information is estimated to average .5 hours per response for each producer, importer, and public member nominated to the Board.

Respondents: Producers, importers, and public member.

Estimated Number of Respondents: 22 for the initial nominations to the Board and approximately 12 respondents annually thereafter.

Estimated Number of Responses per Respondent: 1.

Estimated Total Annual Burden on Respondents: 22 hours for the initial nominations to the Board and 12 hours annually thereafter.

(8) *A requirement to maintain records sufficient to verify reports submitted under the Order.*

Estimate of Burden: Public recordkeeping burden for keeping this information is estimated to average .5 hours per recordkeeper maintaining such records.

Recordkeepers: Handlers and importers.

Estimated number of Recordkeepers: 160.

Estimated Total Recordkeeping Hours: 80 hours.

No comments were received on the recordkeeping requirements.

Background

The Act authorizes the Secretary to establish a national kiwifruit research, promotion, and consumer information program. The program would be funded by an assessment levied on producers and importers not to exceed 10 cents per 7-pound tray of kiwifruit. Kiwifruit sold directly to a consumer by a producer for a purpose other than resale and domestic and imported kiwifruit for processing would be exempt from assessments.

Assessments would be used to pay for: Research, promotion, and consumer information; administration, maintenance, and functioning of the Board; and expenses incurred by the Secretary in implementing and administering the Order, including referendum costs.

The first handler would be responsible for the collection of assessments from the producer and payment to the promotion Board. Handlers would be required to maintain records for each producer for whom kiwifruit is handled, including kiwifruit produced by the handler. In addition, handlers would be required to file reports regarding the collection, payment, or remittance of the assessments. All information obtained through handler reports would be kept confidential.

Customs would collect assessments on imported kiwifruit and would remit those assessments to the promotion Board for a fee.

The Act requires the Department to conduct a referendum during the 60-day period preceding the proposed Order's effective date. Kiwifruit producers of 500 pounds or more and importers of 10,000 pounds or more annually would vote in the referendum to determine whether they favor the Order's implementation. The proposed Order must be approved by a majority of eligible producers and importers voting in the referendum, and producers and importers favoring approval must produce and import more than 50 percent of the total volume of kiwifruit produced and imported by persons voting in the referendum. Subsequent referenda would be conducted every 6 years after the program is in effect or when requested by 30 percent of kiwifruit producers and importers covered by the Order. The Secretary would give serious consideration to requests for referendum when requested by a group representing a considerable amount of the volume covered by the program.

Since the Department has incurred costs in connection with implementing this national research, promotion, and consumer information program for fresh kiwifruit, the Department is requesting the proponents to post, prior to the referendum, a bond or other collateral to cover the Department's costs prior, during, and after referendum. The current estimate for implementation, including the referendum, is $150,000. The Secretary will issue a referendum order, which establishes the voting period, representative period, method of voting, and designates the referendum agents, soon after the bond is posted.

A final rule on the referendum procedures which will be used to conduct the referendum will be published separately.

The Act provides for the submission of proposals for a kiwifruit research, promotion, and consumer information Order by industry organizations or any other interested person affected by the Act. The Act requires that such a proposed Order provide for the establishment of a promotion Board. The promotion Board would be composed of 11 voting members: 6 producers, 4 importers or exporters, and 1 public member. Each member would have an alternate. Members would serve a three-year term of office. No member may serve more than two consecutive three-year terms.

The Act provides that any person subject to the Order may file with the Secretary a petition stating that the Order or any of its provisions is not in accordance with law and requesting a modification of the Order or an exemption from the Order. The individual would be given the opportunity to a hearing on the petition.

The Department issued a news release on May 6, 1996, requesting proposals for an initial Order or portions of an initial Order by May 17, 1996. A second news release, extending the deadline for submission of proposals to June 3, 1996, was issued on May 24, 1996.

An entire proposed Order was submitted by the CKC. The CKC is an industry group created by the State of California to promote California kiwifruit. In addition, a partial proposal was submitted by the New Zealand Kiwifruit Marketing Board (NZKMB). The NZKMB represents all New Zealand exporters of kiwifruit into the United States.

In addition to minor editorial changes, the Department modified the CKC's proposed text by: adding the power and duty to investigate violations of the Act and Order; deleting a definition for industry information because it is not authorized under the Act; revising definitions to make them in accordance with the Act; clarifying that the collection of assessments from imports would be performed through Customs; clarifying that the promotion board would have control over voluntary contributions made to the promotion board; clarifying that the assessment rate may only be changed prior to a fiscal year; clarifying that the assessment rate may only be changed by regulation rather than in the budget; and adding a provision regarding federal debt collection procedures. The CKC also submitted referendum procedures. The final rule on the referendum procedures will be published separately.

A proposed rule seeking comments on a proposed kiwifruit research, promotion, and consumer information order was published on October 2, 1996, in the **Federal Register** [61 FR 51378]. Comments were invited on the CKC proposal for an entire Order (Proposal I), the NZKMB proposals regarding board membership and limiting promotions to the U.S. market (Proposal II), and the NZKMB alternate proposal regarding board membership (Proposal III). The deadline for comments was December 2, 1996. Seventy-five comments were received. Comments were received from eight Chilean kiwifruit growers or grower associations, 31 Chilean kiwifruit exporters or exporter associations, one international exporter association, 26 importers of Chilean kiwifruit, two U.S. growers, the CKC (which represents California growers), four universities, and the embassies of Australia and New Zealand.

The National Kiwifruit Growers Association from Chile submitted a comment in opposition to the proposed order. The same comment was submitted by Fedefruta, a trade association of Chilean fruit growers; the Chilean Fresh Fruit Association (CFFA), a trade association composed of Chilean fruit exporting companies; and the Chilean Exporters Association (CEA), a trade association comprised of Chilean fruit exporting companies. Twenty-nine comments were received from exporters of kiwifruit from Chile that opposed the proposed order and adopted the reasons explained in the comment submitted by the CFFA. Twenty-six comments were received from importers of kiwifruit from Chile that opposed the proposed order. These comments also adopted the rationale in the comment submitted by the CFFA. In addition, six comments were received from growers of kiwifruit from Chile that opposed the proposed order. Three of these comments adopted the reasons explained in the comment submitted by CFFA while the remaining three comments adopted the comment submitted by Fedefruta. Accordingly, in discussing these 59 comments in the preamble, for ease of reference we will refer to them collectively as the Chilean commenters or comments.

The Chilean commenters provided six reasons for their opposition to the proposed order. They were of the view that the proposed program: (1) Was unnecessary to achieve legitimate marketing objectives; (2) would be ineffective in achieving legitimate marketing objectives; (3) was inherently biased against imported kiwifruit; (4) would violate the First Amendment and the Foreign Commerce Clause of the U.S. Constitution; (5) would contravene international principles of free trade embodied in the General Agreement on Tariffs and Trade (GATT); and (6) would violate provisions of the Chilean Constitution that prohibit monopolistic practices.

With regard to the first reason presented, the Chilean commenters argued that the proposed program was unnecessary because the CFFA had been coordinating its promotional activities for kiwifruit in the U.S. market with the CKC by participating in a voluntary funded program; that there was no substantive difference in the objective of the voluntary program and the proposed program; that a trade case brought by the CKC against New Zealand kiwifruit [*California Kiwifruit Commission* v. *Moss,* 53 Cal. Rptr. 2d 138 (Cal. App. 3d Dist. 1996] demonstrated that a mandatory program such as the proposed program could lead to significant abuses and the pursuit of non-marketing objectives; and finally that AMS does not have sufficient data at hand to warrant the imposition of a mandatory order. We disagree with the commenters.

It is the Department's understanding that the voluntary program funded by the CKC and the CFFA was not funded this past year. For a program to be effective, it is necessary that promotional activities be conducted on a regular basis and with no interruptions. Furthermore, it is not the intention of the proposed research and promotion program to obstruct the activities of other promotional activities for kiwifruit. The promotional activities of the CFFA and the CKC could continue independently of the proposed research and promotion program if the parties so desire.

In addition, the proposed program is authorized under the Act and is consistent with the intent and provisions of Act. The program as proposed herein contains all of the necessary and appropriate provisions under the Act needed to conduct a

national program. This program would be subject to similar oversight and supervision as is currently provided for research and promotion programs administered by the Department.

The activities of the proposed Board would be closely monitored by the Department to assure that only authorized activities are funded by the proposed Board. In addition, section 556(e) of the Act [7 U.S.C. 7465] and § 1214.53 of the proposed Order prohibit the use of funds for the purpose of influencing legislation or governmental policy or action. Furthermore, under Title V, Subtitle A of the 1996 Farm Bill (Commodity Promotion and Evaluation), research and promotion program are required to evaluate the accomplishments of their programs. The Department is working with current programs to develop guidelines for the programs to meet the objectives of the required evaluations. If, as a result of the evaluations, a program is determined to not have a positive impact in the industry, those covered by the program would have the necessary information to make a determination on whether to continue the program. Furthermore, a referendum would be conducted to determine the level of support for the program.

The Chilean commenters also argue that the Department should not proceed with a referendum on the proposed order until a decision of the Supreme Court in *Daniel Glickman, Secretary of Agriculture* v. *Wileman Brothers & Elliot, Inc. et al.* (Wileman) [Supreme Court case 95–1184] so that the Department has the benefit of that opinion and is able to conform any proposed order to its requirements.

On June 25, 1997, the Supreme Court decided the case and upheld the constitutionality of generic advertising funded by growers of California nectarines and peaches. The case sought review of First Amendment issues raised in generic advertising programs under Federal marketing orders for California nectarines and peaches. The U.S. Court of Appeals for the Ninth Circuit had previously found that mandatory assessments implicated handlers' First Amendment right because they were compelled to provide financial support for particular generic commercial advertisements. The Supreme Court held that the requirement that growers finance generic advertising does not violate the First Amendment of the Constitution. Consequently, there is no reason to delay the current rulemaking because this program as proposed is consistent with applicable law.

In its second reason for opposing the proposed program, the Chilean commenters argued that a mandatory promotional program could only be successful if a general consensus exists in the affected industry and was of the view that no such consensus exists; that the proposed Order should be substantially altered to conform to GATT principles as are more reflected in the Commodity Promotion, Research, and Information Act of 1996 (generic statute) [7 U.S.C. 7411 *et seq.*]; that the mandatory objectives and the market for domestic kiwifruit producers in the United States were not necessarily the same as that for Chilean kiwifruit; and that the proposed order does not have the necessary safeguards to prevent potential misallocation or biased allocation of funds. We disagree with the commenters' arguments and conclusions. The Order as proposed herein is consistent with applicable law and will be subject to a referendum vote of kiwifruit producers and importers who will be subject to assessments under the Order to determine whether such producers and importers approve and support the implementation of the Order. In addition, the industry has the option of amending the proposed program consistent with the Act in order to reflect the industry's needs at anytime. Furthermore, this program, as are other similar commodity research and promotion programs, will be subject to Department oversight and supervision.

The third reason argued by the Chilean commenters was that the proposed program is inherently biased and discriminates against imported kiwifruit. The comment asserted that this bias is evident throughout the regulation but is most obvious in proposed provisions for adoption of the Order, composition of the board, voting procedure for adopting of assessment and subsequent referenda. The comment went on to conclude that the biases render the proposed Order invalid under the Constitution. We disagree. The proposed program is consistent with the enabling statute.

The commenters then discussed what they view as the most objectionable provisions of the proposed Order that must be modified before a referendum takes place.

The first proposed provision cited was § 1214.30 *Establishment, adjustment, and membership*. The comments asserted that the composition of the Board does not bear any rational relationship to the interests that are subject to assessments. However, the proposed provision is consistent with the relevant statutory provisions that provide for a diverse 11-member Board consisting of six producer members not exempt from assessment; four importer members not exempt from assessment or exporters; and one member appointed from the general public. The Act also provides that, subject to the 11-member limit, the Secretary may adjust membership on the Board to accommodate changes in production and import levels of kiwifruit. However, the proposed order reflects provisions in the Act requiring 51 percent or more of the members of the promotion Board to be domestic producers.

Arguing that unfairness could result from a program controlled by a domestic board representing a minority of the market, the Chilean commenters asserted that in order to avoid a potential for abuse, the provisions of the generic statute concerning geographic representation and provisions concerning periodic reappointment should be invoked. However, these statutory provisions in the generic statute are not part of and do not apply to the kiwifruit statute, the authority for the program proposed herein.

With regard to proposed § 1214.36, *Procedure*, the commenters noted that the voting procedures provide that all motions need only a simple majority vote of a quorum to pass except for approval of an assessment rate which requires a two-thirds vote of a quorum to pass. The commenters pointed out that the Act in § 556(a)(2) [7 U.S.C. 7465] requires a two-thirds vote of a quorum of the board for approval of a budget. We agree, and § 1214.36(b)(2) is revised to reflect the need of a two-thirds vote of a quorum of the board for approval of a budget. The commenters also expressed concern that the four importer members would have a less effective role in setting an assessment rate and budget based on the composition of the Board and the number of votes needed to approve these items. The proposed four importer or exporter members on the Board is consistent with the membership provisions in the Act. A two-thirds vote of a quorum of the board further assures agreement by all parties on budget and assessment rate issues. In addition, the assessment rate would be recommended by the promotion Board and § 556 of the Act [7 U.S.C. 7465] specifies that a budget and assessment rate must be approved by the Secretary before becoming effective. Rulemaking and public comments would be sought by the Department before a final decision is made on the assessment rate.

The Chileans also commented on proposed §§ 1214.39 *Duties*, 1214.40 *Programs, Plans, and Projects*, and

1214.50 *Budget and expenses.* The Chilean commenters argued that, while the specific controls established in these sections are needed to prevent fraud, waste, or abuse in the promotional program, the bureaucratic layer of supervision and expense of a mandatory government-supervised program cause it to be necessarily less efficient than a voluntary program. We disagree and believe that such safeguards contribute to a sound and effective program for the industry. The commenters also stated that the meaning of the term administrative expenses in § 1214.50(f) should be clearly specified. We disagree and believe that the term does not need further clarification in the proposed order. Further, USDA has developed guidelines to identify administrative costs and ensure consistency between programs. These guidelines are being used in other programs.

In commenting on § 1214.51, the Chilean comments asserted that the assessment provisions on imports could operate either as a disguised tariff or as a trade barrier. The commenters argued that domestic producers may default on the payment of assessments whereas importers never will because Customs collects the assessments on imports at the time of entry into the United States. The comments went on to state that, if an initial assessment was set at 10 cents per tray, it would diminish returns to growers in Chile under existing market conditions by 30 percent. The commenters then concluded that a program that uses up 30 percent of a foreign grower's return, without demonstrated market share or price increases, is protectionist. We again disagree with the comment. The statute itself provides for collection of import assessments by Customs. This method of collection is efficient and cost effective and has been used successfully in similar research and promotion programs. We also note that the assessment is imposed on each importer of kiwifruit and not upon the foreign grower.

The comments also expressed concern regarding the board's authority to enter into agreements authorizing state-mandated organizations to collect assessments on its behalf. The comments raised concern about abuse and self-dealing. Any such agreement would be subject to approval of the Secretary and to supervision and oversight. In addition, the proposed promotion Board may or may not decide to utilize a state mandated organization to administer the proposed program. The final issue raised by the comments regarding § 1214.51 was concerning the permitted level of administrative expenses which cannot exceed 30 percent of the budget except in the first year of operation. This provision reflects § 556(c)(3) of the Act [7 U.S.C. 7465] which provides for just such a limitation in the case of assessments.

The CKC commented that the current organization takes great pride in keeping administrative costs at a minimum and that combining the operations of the CKC and the Board would result in substantial savings for all segments of the industry. In addition, the CKC stated that limiting administrative costs would ignore the reality of start-up costs and would tie the hands of future Boards.

The CKC indicated in its comment that it would support a limitation or cap on administrative expenses. The Act provides in § 556(c)(3) [7 U.S.C. 7465] that the level of administrative expenses cannot exceed 30 percent of the budget except in the first year of assessments. The proposed Order reflects that provision of the Act, and, accordingly, no change is made to the proposal as a result of this comment.

The last section discussed by the Chilean comments was § 1214.71 *Suspension or termination.* The commenters were of the view that the provision reflected a structural and discriminatory bias in the regulation against imported kiwifruit. The comments suggested that to correct this problem the votes should be weighted to reflect the number of growers that each importer represents. We disagree. The voting levels provided for in the proposed order concerning suspension or termination reflect the provisions of § 561 of the Act [7 U.S.C. 7470]. Not only does suspension or termination have to be favored by a majority of the producers and importers voting in the referendum, but those producers and importers must also produce or import more than 50 percent of the total volume of kiwifruit produced or imported by persons voting in the referendum. Further, the Secretary is authorized to suspend or terminate the operation of an order or provision if the Secretary finds that it obstructs or does not tend to effectuate the purposes of the Act.

In their fourth, fifth, and sixth reasons for opposing the proposed order, the Chilean commenters argued that the proposed program would violate several provisions of the United States Constitution, provisions of GATT, and lastly principles embodied in the Constitution and laws of Chile.

With regard to the U.S. Constitution, the comments identified not only violations of the First Amendment and Foreign Commerce Clause but also argued violations of the Import-Export Clause, the Interstate Commerce Clause, the Equal Protection Clause, and the Separation of Powers Principle. The comments argued that the proposed order violated the national treatment provision of the GATT by treating imported kiwifruit less favorably than domestic kiwifruit. We disagree and are of the view that the proposed program is consistent with its authorizing statutory provisions and the applicable law. Under the proposed program, producers and importers of kiwifruit would pay an equal assessment to support a generic program of research and promotion for kiwifruit.

The commenters also argued that the proposed program is contrary to free market principles embodied on the Constitution of Chile, noting that mandatory assessments for generic promotion are not legal in Chile. The commenters stated that without appropriate credit for voluntary contributions, Chilean interests may be forced to mount legal challenges. We do not believe that this rulemaking action raises any pertinent legal issues with regard to the Constitution and laws of Chile. Furthermore, the Act does not authorize credit for voluntary or mandatory contributions to other programs.

In conclusion, the Chilean commenters state that the Department should not submit the proposed Order to a referendum. However, if it is submitted to referendum, the commenters stated that the proposed Order should conform to GATT principles and the statutory limitations for programs under the generic statute and should be modified to address the concerns raised in the comment. The comment goes on to state that the Department should refrain from further action on this rulemaking until opinions are rendered in the Wileman and Moss cases.

In response to the Chilean commenters, for the reasons previously discussed, the Department is continuing with this rulemaking but has modified the proposed rule in § 1214.36 (b)(1) and (b)(2), based on the comments.

A comment was received from the New Zealand Embassy on behalf of the New Zealand Government. That comment supported Proposal II and the alternate Proposal III. Proposal II, in part, stated that two of the four importer/exporter seats on the promotion Board should be filled with New Zealand exporters since this country has been the major exporting country into the U.S. for the past 10 years. Proposal III stated that promotional expenditures of the exporting countries for the last 10 years

should be considered when assigning seats on the promotion Board. In addition, the comment expressed strong reservations concerning the proposed Order, and other similar schemes, on the grounds that: (1) New Zealand exporters and their import agents would have to contribute to funding domestic promotions with their related administrative costs; (2) funds collected from New Zealand exporters would be used to fund U.S. exports of kiwifruit to third markets in direct competition with New Zealand's interests; (3) the proliferation of checkoff schemes such as the proposed order would encourage other countries to levy importers in order to introduce similar schemes; and (4) there appears to be some question about the World Trade Organization (WTO) consistency of the checkoff schemes in general, particularly in relation to the discrimination involved in using foreign contributions to fund the marketing of domestic products.

We disagree with the commenter. All producers and importers under the proposed Order would contribute to generic program of research, promotion, and consumer information. Such a program is intended to maintain, expand, and develop markets for kiwifruit. The proposed Order does specifically provide that all promotions are to be generic in nature without attribution to origin. Further, an amendment to the proposed Order to address concerns raised by the Government of Australia and the NZKMB would add a provision to the Order to limit promotions to the U.S. domestic market. Accordingly, we believe that the proposed Order would benefit both domestic and imported kiwifruit alike, consistent with applicable law including the WTO. With regard to the commenters concern regarding actions of other countries to levy importers in order to introduce similar scheme, we believe that such a view is speculative and as such we cannot offer an opinion of what a particular country might do. Accordingly, we disagree with this part of the comment.

The New Zealand Embassy also stated that representation of importers on the Board should be based on promotion expenditures by the exporting countries in the United States. In its comment concerning this issue, the CKC stated that there is no reasonable way to verify foreign countries' expenditures on advertising and marketing in the U.S. Further, the CKC expressed its views opposing the NZKMB proposal to provide in the Order that the Secretary ensure that at least two of the four importers/exporters member seats be selected from nominees nominated by importers and/or exporters of New Zealand kiwifruit. It also expressed concern regarding any proposal to limit the importer positions to import or export who have no domestic production interests.

We agree that it would be very difficult to verify the promotional expenditures of each country in the U.S. Further, this would not be a reasonable measure to determine the number of importer members on the Board. The Department believes that the Secretary should have the latitude to appoint representatives to the Board in a manner that best reflects the interests of the various importer and/or exporter segments. Accordingly, this part of proposal II and all of proposal III are denied.

A comment was received from the Embassy of Australia concerning the proposed Order. The Australian Government indicated that it welcomed certain elements of the proposed program. First, the commenter noted that the proposed program would treat domestically produced and imported kiwifruit equitably by using assessment collected to undertake generic promotion for the whole industry. Second, there would be an equitable spread of representation on the Board. Third, the comment looked favorably on the exemption for importers of less than 10,000 pounds a year and kiwifruit sold for processing and the referendum to be conducted before the program would be implemented.

The comment, however, did raise a concern if the generic promotion activities discriminated against counter-seasonal produce and/or importers. The commenter stated that it would be concerned if assessments were used for the promotion of kiwifruit in competing export markets. The comment concluded that assessments should be used for the generic promotion of kiwifruit in the United States only.

Part of Proposal II recommended that all promotions be intended to promote kiwifruit consumption in the U.S. domestic market and not U.S.-produced kiwifruit in foreign markets.

We believe that these two concerns have merit. To avoid any negative effects of seasonal promotion, proposed § 1214.40, *Programs, plans, and projects,* is revised to include a new paragraph (e) to require that promotions be conducted all year round to promote kiwifruit during all seasons which would result in kiwifruit from all countries being promoted equitably. In addition, the Department is adopting this part of Proposal II and a new paragraph (f) is added to provide that all programs established by the Board with the approval of the Secretary will be required to promote kiwifruit consumption on the U.S. domestic market and that no program could promote exports of U.S. produced kiwifruit in foreign markets. Section 557(e) of the Act [7 U.S.C. 7466] provides for the use of funds to be used for the development and expansion of sales in foreign markets of kiwifruit produced in the United States. However, this provision is permissive and not required to be in an Order. Accordingly, we believe that the most effective use of funds based upon the evidence in the rulemaking would be to limit the use of assessments to domestic promotion only.

In its comment concerning the proposed order, the Southern Hemisphere Association of Fresh Fruit Exporters opposed its implementation because it is contrary to the free trade principles embodied in the Uruguay Round of GATT. The commenter was of the view that the Order would restrict free market access and would operate as a non-tariff barrier to trade. The comment also stated that the restrictive trade effects of the proposed Order were apparent from its essential provision and noted that the proposed Order was drafted by the CKC. The comment went on to state that: (1) The proposed Order was anti-competitive in that it would divert funds from promotional programs of individual companies or countries and would operate as an anti-competitive non-tariff trade barrier; (2) the mandatory aspects of the order conflict with the domestic trade laws of many countries; (3) such mandatory programs are now subject to legal review in the Supreme Court on constitutional grounds; and (4) the implementation of the proposed Order would set a precedent for adoption of similar orders in other countries.

We disagree with the commenter's views and conclusions. As discussed previously in responding to similar comments received, we are of the view that the proposed Order is consistent with applicable law including the GATT. We again note the Supreme Court in Wileman held in favor of the government with regard to the constitutional arguments. We offer no view with regard to the domestic trade laws of the countries as to whether other countries would adopt similar programs.

The CKC commented on the proposed Order and Proposals II and III. The CKC comments regarding Proposals II and III were discussed previously.

With regard to § 1214.36(b)(2), the CKC stated that it would support a

three-quarters of a quorum requirement for votes on budget and assessment rate issues rather than the proposed two-thirds requirement. Referencing the CEA comment about adopting the voting provision contained in the generic statute, the commenter supported accommodating the Chilean concern by changing the two-thirds requirement to three-quarters and adopting by-laws to assure that there is near unanimous agreement among all interests on assessment and budget issues. However, the Act provides for the vote of two-thirds of a quorum of the Board for both budget and assessment recommendations to the Secretary. Accordingly, this proposed change is not adopted and the Order will provide for the percentages that are required by the Act.

As to § 1214.39(l), which specifies duties of the Board, the CKC would support a provision on the Order to prohibit the Promotion Board from making expenditures in any market other than the United States. This concern has been previously addressed in response to a comment received by the Australian Government and, as a result, § 1214.40 would be revised to include a new paragraph (f) to limit promotions of kiwifruit consumption to the U.S. domestic market.

The CKC raised concern about other commenters requesting that the proposal include a provision concerning credits. While expressing a lack of understanding of what purpose a generic credit would have, the CKC indicated that it would oppose a brand credit. The Act does not authorize credits for such expenditures.

Seven comments were received concerning the definition of kiwifruit as proposed in § 1214.8. Four of the comments were received from university professors, Extension Service personnel at Clemson University, Cornell University, Ohio State University, and Oregon State University, and from two growers of kiwifruit. In addition, the CKC commented on that section of the proposal.

Both the Act and the proposed Order define kiwifruit as all varieties of fresh kiwifruit grown in or imported into the United States. The university commenters requested that the definition of kiwifruit be revised to include only the species *Actinidia deliciosa.* They pointed out that this is the predominant species with one commenter noting that this species controls over 95 percent of the domestic market. There are other species of kiwifruit. These commenters all expressed concerns regarding the species *Actinidia arguta* or hardy kiwifruit. One comment noted that while the inside of the fruit was similar to *Actinidia deliciosa,* this was really the only similarity. Exterior appearance, harvesting, production areas (Oregon, Washington, and Pennsylvania), production levels (an estimated 100,000 flats in the next 5 years), and marketing are all different.

The university commenters were concerned about the impact of the proposed Order on hardy kiwifruit producers. Two of the commenters suggested that, if such kiwifruit is assessed, then a percentage of funds should be earmarked for research and development of this new crop of hardy kiwifruit. The two grower comments also raised concerns regarding the definition of kiwifruit in the proposed Order. One grower opposed the inclusion of hardy kiwifruit grown in the State of Pennsylvania and stated that the Order should be limited to the State of California. The second grower raised issues similar to the university comments concerning hardy kiwifruit.

We agree that the species *Actinidia arguta* is a different species from the most common known *Actinidia deliciosa* or fuzzy kiwifruit. Therefore, the definition of kiwifruit was changed in the proposed order to mean all varieties of the fresh kiwifruit classified under the species *Actinidia deliciosa* or the genus *Actinidia,* whose fruit is a large berry, oval in shape, with a brown skin covered in hairs, which are grown in or imported into the United States. This definition would exclude the species *Actinidia arguta* also known as ''hardy'' kiwifruit from coverage under the program.

In its comment the CKC was in favor of the assessment being levied on all varieties that are referred to as ''Kiwifruit or Kiwi'' but stated that it would support a provision to allow the Board to exempt certain varieties due to their limited volume, perhaps under 80,000 pounds of total domestic production, differences in appearance, or other reasons.

Section 556(b)(5) of the Act [7 U.S.C. 7465] does provide for exemptions from assessment for producers who produce less than 500 pounds of kiwifruit per year, importers who import less than 10,000 pounds of kiwifruit a year, sales of kiwifruit made directly from the producer to a consumer for a purpose other than resale, and the production or importation of kiwifruit for processing. No other exemption is authorized in the Act. In addition, the proposed order will cover all varieties of kiwifruit under the *Actinidia deliciosa* species that meet the exemption levels.

In summary, § 1214.8, § 1214.36(b)(1) and (2), and § 1214.40 have been revised as a result of comments received.

Section 1214.8 was revised to define kiwifruit as all varieties of fresh kiwifruit classified under the species *Actinidia deliciosa.*

Section 1214.36(b)(2) was revised to require a two-third vote of a quorum for budget issues.

In § 1214.40, a new paragraph (e) was added to specify that promotions shall be conducted all year round. Also, a new paragraph (f) was added to this section to prohibit the use of funds for promotional activities in other countries.

There were no other changes to the proposed Order as a result of the comments received on the text of the Order provisions as they were proposed in the October 2, 1996, issue of the **Federal Register**.

For the Order to become effective, the Order must be approved by a majority of kiwifruit producers and importers voting in a referendum, with such majority producing or importing more than 50 percent of the total volume of kiwifruit produced and imported by persons voting in the referendum.

The proposed Order is summarized as follows:

Sections 1214.1 through 1214.19 of the proposed Order define certain terms, such as kiwifruit, handler, producer, and importer, which are used in the proposed Order.

Sections 1214.30 through 1214.39 include provisions relating to the establishment, adjustment, and membership; nominations; appointment; terms of office; vacancies; reimbursement; powers; and duties of the Board.

The Board would be the body organized to administer the Order through the implementation of programs, plans, projects, budgets, and contracts to promote and disseminate information about kiwifruit, under the supervision of the Secretary. Further, the Board would be authorized to incur expenses necessary for the performance of its duties and to set a reserve fund. Sections 1214.40 and 1214.50 provide information on these activities.

Sections 1214.51 through 1214.53 would authorize the collection of assessments, specify who pays them and how, and specifies persons who would be exempt from paying the assessment. In addition, it would prohibit use of funds to influence government policy or action.

The assessment rate may not exceed 10 cents per 7-pound tray of kiwifruit. The actual rate would be recommended by the Board and approved by the

Secretary through regulation. Direct sales to consumers by a producer and kiwifruit for processing are exempt from assessments.

The assessment sections also outline the procedures to be followed by handlers and importers for remitting assessments; establish a 1.5 percent per month interest charge for unpaid or late assessments; and provide for refunds of assessments paid by importers who import less than 10,000 pounds of kiwifruit a year.

Sections 1214.60 through 1214.62 concern reporting and recordkeeping requirements for persons subject to the Order and protect the confidentiality of information obtained from such books, records, or reports.

Sections 1214.70 through 1214.73 describe the rights of the Secretary, authorize the Secretary to suspend or terminate the Order when deemed appropriate, and prescribe proceedings after suspension or termination.

Sections 1214.74 through 1214.77 are miscellaneous provisions including the provisions involving personal liability of Board members and employees; handling of patents, copyrights, inventions, and others; amendments to the Order; and separability of Order provisions.

List of Subjects in 7 CFR Part 1214

Administrative practice and procedure, Advertising, Consumer information, Marketing agreements, Kiwifruit, Promotion, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, it is proposed that Title 7 of Chapter XI of the Code of Federal Regulations be amended as follows:

1. Part 1214 is added to read as follows:

PART 1214—KIWIFRUIT RESEARCH, PROMOTION, AND CONSUMER INFORMATION ORDER

Subpart A—Kiwifruit Research, Promotion, and Consumer Information Order

Definitions

National Kiwifruit Board

Promotion, Research, and Consumer Information and Industry Information

Expenses and Assessments

Reports, Books, and Records

Miscellaneous

Subpart B—Rules and Regulations

Definitions

Nomination Procedures

General

Assessments

Reports

Miscellaneous

Authority: 7 U.S.C. 7461–7473.

Subpart A—Kiwifruit, Research, Promotion, and Consumer Information Order

Definitions

§ 1214.1 Act.

Act means the National Kiwifruit Research, Promotion, and Consumer Information Act, subtitle D of title V of the Federal Agricultural Improvement and Reform Act of 1996, Public Law 104–127, 7 U.S.C. 7461–7473, and any amendments thereto.

§ 1214.2 Consumer information.

Consumer information means any action taken to provide information to, and broaden the understanding of, the general public regarding the consumption, use, nutritional attributes, and care of kiwifruit.

§ 1214.3 Department.

Department means the United States Department of Agriculture.

§ 1214.4 Exporter.

The term *exporter* means any person outside the United States who exports kiwifruit into the United States.

§ 1214.5 Fiscal year.

Fiscal year means the 12-month period from October 1 to September 30 each year, or such other period as recommended by the Promotion Board and approved by the Secretary.

§ 1214.6 Handler.

Handler means any person, excluding a common carrier, engaged in the business of buying and selling, packaging, marketing, or distributing kiwifruit as specified in the Order.

§ 1214.7 Importer.

Importer means any person who imports kiwifruit into the United States.

§ 1214.8 Kiwifruit.

Kiwifruit means all varieties of fresh kiwifruit classified under the species *Actinidia deliciosa* or the genus *Actinidia*, whose fruit is a large berry, oval in shape, with a brown skin covered in hairs, which are grown in or imported into the United States.

§ 1214.9 Marketing.

Marketing means to sell or otherwise dispose of kiwifruit into interstate, foreign, or intrastate commerce by buying, marketing, distribution, or otherwise placing kiwifruit into commerce.

§ 1214.10 Part and subpart.

Part means this kiwifruit research, promotion, and consumer information order and all rules and regulations and

supplemental orders issued thereunder, and the term subpart means the kiwifruit research, promotion, and consumer information order.

§ 1214.11 Person.

Person means any individual, group of individuals, partnership, corporation, association, cooperative, or other legal entity.

§ 1214.12 Processing

Processing means kiwifruit that are commercially canned, fermented, distilled, extracted, preserved, ground, crushed or processed in such manner as the Promotion Board, with the approval of the Secretary, may determine.

§ 1214.13 Producer.

Producer means any person who grows kiwifruit in the United States for sale in commerce.

§ 1214.14 Programs, plans, and projects.

Programs, plans, and projects means promotion, research, and consumer information plans, studies, projects, or programs conducted pursuant to this part.

§ 1214.15 Promotion.

Promotion means any action taken under this Order including paid advertising, to present a favorable image for kiwifruit to the general public for the purpose of improving the competitive position of kiwifruit and stimulating the sale of kiwifruit.

§ 1214.16 Promotion Board.

Promotion Board means the administrative body referred to as the National Kiwifruit Board or otherwise named Kiwifruit Promotion Board or Promotion Board established under § 1214.30.

§ 1214.17 Research.

Research means any type of research relating to the use, nutritional value, and marketing of kiwifruit conducted for the purpose of advancing the image, desirability, marketability, or quality of kiwifruit.

§ 1214.18 Secretary.

Secretary means the Secretary of Agriculture of the United States or any other officer or employee of the Department to whom the authority has heretofore been delegated, or to whom authority may hereafter be delegated, to act in the Secretary's stead.

§ 1214.19 United States.

United States means the 50 states of the United States, the District of Columbia, and the Commonwealth of Puerto Rico.

National Kiwifruit Board

§ 1214.30 Establishment, Adjustment, and membership.

(a) Establishment of National Kiwifruit Board. There is hereby established a National Kiwifruit Board of 11 members appointed by the Secretary as follows:

(1) Six members who are producers (or their representatives) and who are not exempt from an assessment.

(2) Four members who are importers (or their representatives) and who are not exempt from an assessment, or are exporters (or their representatives).

(3) One member appointed from the general public.

(b) Adjustment of Membership.

(1) Subject to the 11 member limit, the Secretary may adjust membership on the Promotion Board to accommodate changes in production and import levels of kiwifruit, so long as producers comprise not less than 51 percent of the membership of the Board.

(2) At least every five years, and not more than every three years, the Promotion Board shall review changes in the volume of domestic and imported kiwifruit. If the annual kiwifruit production and imports over the preceding four years, indicate that such changes in production and import levels have occurred warranting reapportionment, the Promotion Board shall recommend reapportionment of Board membership subject to the 51 percent requirement, for approval of the Secretary.

(3) In determining the volume of kiwifruit produced in the United States or imported into the United States for purposes of this section, the Promotion Board and the Secretary shall:

(i) Only consider kiwifruit produced or imported by producers and importers, respectively, as those terms are defined in § 1214.13 and 1214.7; and

(ii) Use the information received by the Promotion Board under § 1214.60, and data published by the California Kiwifruit Commission, U.S. Department of Commerce import statistics and other government kiwifruit production data.

(c) Appointment and nomination.

(1) *Appointment.* The Secretary shall appoint the members of the Promotion Board from nominations submitted in accordance with this section.

(i) Producers shall be appointed from individuals nominated by producers.

(ii) Importers and exporters shall be appointed from individuals nominated by importers and/or exporters.

(iii) The public representative shall be appointed from nominations submitted by the Promotion Board.

(iv) If producers, importers, or exporters fail to nominate individuals for appointment, the Secretary shall appoint members in the manner specified in § 1214.31. If the Promotion Board fails to nominate a public representative, such member may be appointed by the Secretary without a nomination.

(2) The Secretary shall appoint an alternate for each member of the Promotion Board. Alternates shall:

(i) Be appointed in the same manner for whom such individual is an alternate; and

(ii) Serve on the Promotion Board as a voting member if such member is absent or disqualified.

(3) For purposes of the provisions of this section relating to the appointment of producers and importers or exporters to serve on the Promotion Board, the term producer, importer, or exporter refers to any person who is a producer, importer, or exporter, respectively, or if the producer, importer, or exporter is an entity other than an individual, an individual who is an officer or employee of such producer, importer, or exporter. Persons who qualify to serve as either a producer member or an importer member must select the industry group that they want to represent.

§ 1214.31 Nominations.

All nominations for appointments to the Promotion Board under § 1214.33 shall be made as follows:

(a) As soon as practicable after this subpart becomes effective, nominations for appointment to the initial Promotion Board shall be obtained from producers and importers or exporters by the Secretary. In any subsequent year in which an appointment to the Promotion Board is to be made, nominations for positions whose terms will expire at the end of that year shall be obtained from producers, and as appropriate, importers or exporters, and certified as eligible candidates by the Promotion Board and submitted to the Secretary by May 1 of such year, or such other date as approved by the Secretary.

(b) Nominations shall be made through mail ballot in accordance with procedures prescribed in this section.

(c) Except for initial Promotion Board members, whose nomination process will be initiated by the Secretary, the Promotion Board shall issue a call for nominations by March 1 of each year in which nominations for an appointment to the Promotion Board is to be made. The call shall include, at a minimum, the following information:

(1) A list by importer/exporter and producer category of the vacancies for which nominee may be submitted.

(2) The date by which the names of nominees shall be submitted for consideration to be in compliance with paragraph (a) of this section.

(3) Nominations for each position shall be made by mail. Nomination forms shall be mailed to all known producers, importers in the United States, and kiwifruit exporters and/or exporter organizations where possible. The nomination form shall have attached to it the requirements of the position, term, eligibility requirements, and the Department's equal opportunity policy. Except with respect to nominations for the initial appointments to the Promotion Board, publicizing the nomination process and vacant positions shall be the responsibility of the Promotion Board.

(4) All producers, importers within the United States, and exporters may participate in the nomination process. However, if a producer is engaged in the production of kiwifruit and is also an importer, such person's participation shall be limited to one vote. The following nomination process shall be followed:

(i) Nomination forms shall be sent to all known producers, importers, or exporters. The Promotion Board shall determine the eligibility and willingness to serve of all names of the individuals listed on the nomination forms returned to the Promotion Board. The names of the individuals who are eligible and willing to serve will be listed on a selection ballot. The selection ballot will be sent to all known producers and importers for final selection of the nominees to be sent to the Secretary. Exporters will not be sent a selection ballot.

(ii) Each nominee shall meet the qualifications set forth in this part.

(iii) If a producer nominee is engaged in the production of kiwifruit and is also an importer, such individual shall participate within the category that such individual so elects in writing to the Promotion Board and such election shall remain controlling until revoked in writing to the Promotion Board.

(d) When producers or importers are voting for nominees to the Promotion Board the following provisions shall apply:

(1) Voting for any open position shall be on the basis of one vote per eligible voter.

(2) Producers will vote for producer positions and importers will vote for importer and exporter positions only.

(3) Whenever the producers or importers are choosing nominees for one open position on the Promotion Board, the proposed nominee with the highest and second highest number of votes cast shall be the nominees submitted to the Secretary.

(4) Each open position will be a separate position. Alternate and member selections will also be held as separate positions. A person shall only be nominated for one open member or alternate position.

(5) Voters shall certify on their ballots as to their eligibility. Such certification may be subject to verification.

(e) The Secretary may reject any nominee submitted. If there are insufficient nominees from which to appoint members to the Promotion Board as a result of the Secretary's rejecting such nominees, additional nominees shall be submitted to the Secretary under the procedures set out in this section.

(f) Whenever producers or importers fail to nominate individuals for an open position on the Promotion Board under the preceding provisions of this section the Secretary may appoint members in such manner as the Secretary determines appropriate.

§ 1214.32 Acceptance.

Each individual nominated for membership on the Promotion Board shall qualify by filing a written acceptance with the Secretary at the time of nomination. Such acceptance shall represent the nominee's willingness to serve if selected and to operate in accordance with the provisions of this part.

§ 1214.33 Appointment.

From the nominations made pursuant to this subpart, the Secretary shall appoint the members and alternates.

§ 1214.34 Term of office.

(a) The members and alternates of the Promotion Board shall serve for terms of three years, except that five members and their alternates appointed to the initial Promotion Board shall be appointed for a term of two years and six members and their alternates shall be appointed for a term of three years.

(b)(1) Except with respect to terms of office of the initial Promotion Board, the term of office for each member and alternate of the Promotion Board shall begin on July 1 or such other date that may be approved by the Secretary.

(2) The term of office for the initial Promotion Board shall begin immediately following appointment by the Secretary, except that time in the interim period from appointment until the following July 1, or such other date that is the generally applicable beginning date for terms under paragraph (b)(1) of this section approved by the Secretary, shall not count toward the tenure limitation of office.

(c) Promotion Board members shall serve during the term of office for which they are appointed and have qualified, and until their successors are appointed and have qualified.

(d)(1) No member shall serve more than two successive three-year terms, except as provided in paragraph (d)(2) of this section and § 1214.35(b)(1). Members serving two consecutive three-year terms are eligible to serve as alternates, and alternates serving two consecutive three-year terms are eligible to serve two three-year terms as members.

(2) Those members serving initial terms of two years may serve one successive three-year term.

§ 1214.35 Vacancies.

(a) To fill any vacancy occasioned by the death, removal, resignation, or disqualification of any member of the Promotion Board, the alternate of that member shall automatically assume the position of said member. If an alternate member position becomes vacant, the Secretary shall appoint an alternate member in the manner specified in § 1214.31. Each successor appointment shall be for the remainder of the term vacated. A vacancy will not be required to be filled if the unexpired term is less than six months.

(b)(1) No successor appointed to a vacated term of office shall serve more than two successive three-year terms on the Promotion Board, except as provided in paragraph (b)(2)(ii) of this section.

(2)(i) Any successor serving longer than one year may serve one successive three-year term.

(ii) Any successor serving one year or less may serve two successive three-year terms.

(c) If a member of the Promotion Board consistently refuses to perform the duties of a member of the Promotion Board, or if a member of the Promotion Board is engaged in acts of dishonesty or willful misconduct, the Promotion Board may recommend to the Secretary that the member be removed from office. If the Secretary finds the recommendation of the Promotion Board shows adequate cause, the Secretary shall remove such member from office. Further, without recommendation of the Promotion Board, a member may be removed by the Secretary upon showing of adequate cause, including the failure by a member to submit reports or remit assessments required under this part, if the Secretary determines that such member's continued service would be detrimental to the achievement of the purposes of the Act.

§ 1214.36 Procedure.

(a) At a properly convened meeting of the Promotion Board, a majority of the members shall constitute a quorum.

(b) Each member of the Promotion Board will be entitled to one vote on any matter put to the Promotion Board. At assembled meetings of the Promotion Board, all votes will be cast in person.

(1) A motion, except motions to set an assessment rate and motion to approve a budget, will carry if supported by a simple majority of those voting.

(2) Motions to establish an assessment rate and motions to approve a budget shall require a two-thirds vote of a quorum of the Promotion Board for passage.

(c) Meetings of the Promotion Board may be conducted by other means of communications, provided that each member is given prior notice of the meeting and has an opportunity to be present either physically or by electronic connection.

(d) In lieu of voting at a properly convened meeting and, when in the opinion of the chairperson of the Promotion Board such action is considered necessary, the Promotion Board may take action upon the concurring votes of a majority of its members by mail, telephone, electronic mail, facsimile, or any other means of communication, and, if appropriate, confirmed promptly in writing. In that event, all members must be notified and provided the opportunity to vote. Any action so taken shall have the same force and effect as though such action had been taken at a properly convened meeting of the Promotion Board. All votes shall be recorded in Promotion Board minutes.

(e) The organization of the Promotion Board and the procedures for conducting meetings of the Promotion Board shall be in accordance with its bylaws, which shall be established by the Promotion Board and approved by the Secretary.

§ 1214.37 Compensation and reimbursement.

The members and alternate members of the Promotion Board shall serve without compensation but shall be reimbursed for necessary and reasonable expenses or a reasonable per diem allowance, as approved by the Promotion Board and the Secretary, incurred by such members in the performance of their responsibilities under this subpart.

§ 1214.38 Powers.

The Promotion Board shall have the following powers:

(a) To receive and evaluate or, on its own initiative, develop and budget for proposed programs, plans, or projects to promote the use of kiwifruit, as well as proposed programs, plans, or projects for research and consumer information, and to make recommendations to the Secretary regarding such proposals;

(b) To administer the provisions of this subpart in accordance with its terms and provisions;

(c) To appoint or employ such individuals as it may deem necessary, define the duties, and determine the compensation of such individuals. The Board shall seek, to the extent possible, to employ or contract with personnel who are already associated with state chartered organizations involved in promoting kiwifruit;

(d) To make rules and regulations to effectuate the terms and provisions of this subpart;

(e) To receive, investigate, and report to the Secretary for action complaints of violations of the provisions of this subpart;

(f) To establish committees and subcommittees of Promotion Board members, including an executive committee whose powers and membership shall be determined by the Promotion Board, subject to the approval of the Secretary, and to adopt such bylaws and other rules for the conduct of its business as it may deem advisable;

(g) To establish committees which may include individuals other than Promotion Board members, and pay the necessary and reasonable expenses and fees for the members of such committees;

(h) To recommend to the Secretary amendments to this subpart;

(i) With the approval of the Secretary, to enter into contracts or agreements for the development and conduct of programs, plans, or projects authorized under § 1214.40 and for other services necessary for the implementation of this subpart, and for the payment of the cost thereof with funds collected and received pursuant to this subpart. The Promotion Board shall not contract with any person covered by the program or serving on the promotion board for the purpose of kiwifruit programs, plans, or projects. Any contract or agreement shall provide that:

(1) The contractor or agreeing party shall develop and submit to the Promotion Board a program, plan, or project together with a budget or budgets that shall show the estimated cost to be incurred for such program, plan, or project;

(2) Any such program, plan, or project shall become effective upon approval of the Secretary;

(3) The contracting or agreeing party shall keep accurate records of all of its transactions and make periodic reports to the Promotion Board of activities conducted, submit accounting for funds received and expended, and make such other reports as the Secretary or the Promotion Board may require; and the Secretary may audit the records of the contracting or agreeing party periodically; and

(4) Any subcontractor who enters into a contract with a Promotion Board contractor and who receives or otherwise uses funds allocated by the Promotion Board shall be subject to the same provisions as the contractor;

(j) With the approval of the Secretary, to invest, pending disbursement pursuant to a program, plan, or project, funds collected through assessments provided for in § 1214.51, and any other funds received by the Promotion Board in, and only in, obligations of the United States or any agency thereof, in any interest-bearing account or certificate of deposit of a bank that is a member of the Federal Reserve System, or in obligations fully guaranteed as to principal and interest by the United States;

(k) To require its employees to receive, investigate, and report to the Secretary complaints of violations of this part; and

(l) Such other powers as may be approved by the Secretary.

§ 1214.39 Duties.

The Promotion Board shall have the following duties:

(a) To meet not less than two times per year, and to organize and select from among its members a chairperson and such other officers as may be necessary;

(b) To evaluate or develop, and submit to the Secretary for approval, promotion, research, and consumer information programs, plans or projects;

(c) To prepare for each fiscal year, and submit to the Secretary for approval at least 60 days prior to the beginning of each fiscal year, a budget of its anticipated expenses and disbursements in the administration of this subpart and a marketing plan with all the programs, plans, and projects as provided in §§ 1214.40 and 1214.50;

(d) To maintain such books and records, which shall be available to the Secretary for inspection and audit, and to prepare and submit such reports from time to time to the Secretary, as the Secretary may prescribe, and to make appropriate accounting with respect to

the receipt and disbursement of all funds entrusted to it;

(e) To prepare and make public, at least annually, a report of its activities carried out, and an accounting for funds received and expended;

(f) To cause its financial statements to be prepared in conformity with generally accepted accounting principles and to be audited by an independent certified public accountant in accordance with generally accepted auditing standards at least once each fiscal year and at such other times as the Secretary may request, and submit a copy of each such audit to the Secretary;

(g) To give the Secretary the same notice of meetings of the Promotion Board as is given to members in order that the Secretary, or a representative of the Secretary, may attend such meetings;

(h) To submit to the Secretary such information as may be requested pursuant to this subpart;

(i) To keep minutes, books, and records that clearly reflect all the acts and transactions of the Promotion Board. Minutes of each Board meeting shall be promptly reported to the Secretary;

(j) To act as intermediary between the Secretary and any industry member;

(k) To follow the Department's equal opportunity/civil rights policies;

(l) To work to achieve an effective, continuous, and coordinated program of promotion, research, consumer information, evaluation and industry information designed to strengthen the kiwifruit industry's position in the marketplace, maintain and expand existing markets and uses for kiwifruit, develop new markets and uses for kiwifruit, and to carry out programs, plans, and projects designed to provide maximum benefits to the kiwifruit industry;

(m) To conduct periodic review or evaluation of each program, plan, or project to ensure that it contributes to an effective program of research, promotion, and consumer information;

(n) Not less than every 5 years, authorize and fund, from funds otherwise available to the Promotion Board, an independent evaluation of the effectiveness of the programs conducted by the Promotion Board. The Promotion Board shall submit to the Secretary, and make available to the public, the results of each periodic independent evaluation conducted under this section; and

(o) To investigate violations of the Order and report the results of such investigations to the Secretary for appropriate action to enforce the provisions of the Order.

Promotion, Research, and Consumer Information

§ 1214.40 Programs, plans, and projects.

(a) The Promotion Board shall receive and evaluate, or on its own initiative develop, and submit to the Secretary for approval any program, plan, or project authorized under this subpart. Such programs, plans, or projects shall provide for:

(1) The establishment, issuance, effectuation, and administration of appropriate programs for promotion, research, and consumer information with respect to kiwifruit; and

(2) The establishment and conduct of research with respect to the use, nutritional value, sale, distribution, and marketing, of kiwifruit and kiwifruit products, and the creation of new products thereof, to the end that marketing and use of kiwifruit may be encouraged, expanded, improved, or made more acceptable and to advance the image, desirability, or quality of kiwifruit.

(b) No program, plan, or project shall be implemented prior to its approval by the Secretary. Once a program, plan, or project is so approved, the Promotion Board shall take appropriate steps to implement it.

(c) Each program, plan, or project implemented under this subpart shall be reviewed or evaluated periodically by the Promotion Board to ensure that it contributes to an effective program of promotion, research, or consumer information. If it is found by the Promotion Board that any such program, plan, or project does not contribute to an effective program of promotion, research, or consumer information, then the Promotion Board shall terminate such program, plan, or project.

(d) No program, plan, or project shall make any false claims on behalf of kiwifruit or use unfair or deceptive acts or practices with respect to the quality, value, or use of any competing product. Kiwifruit of all origins shall be treated equally. All promotions shall be generic in nature.

(e) Promotions shall be conducted to promote kiwifruit during all seasons and from all countries.

(f) All programs developed and implemented by the Board shall promote kiwifruit consumption in the U.S. domestic market. No program shall be implemented by the Board to promote exports of U.S.-produced kiwifruit in foreign markets.

Expenses and Assessments

§ 1214.50 Budget and Expenses

(a)(1) At least 60 days prior to the beginning of each fiscal year, and as may be necessary thereafter, the Promotion Board shall prepare and submit to the Secretary a budget for the fiscal year covering its anticipated expenses and disbursements in administering this subpart. Each such budget shall include:

(i) A statement of objectives and strategy for each program, plan, or project;

(ii) A summary of anticipated revenue, with comparative data for at least one preceding year;

(iii) A summary of proposed expenditures for each program, plan, or project; and

(iv) Staff and administrative expense breakdowns, with comparative data for at least one preceding year.

(2) Each budget shall provide adequate funds to defray its proposed expenditures and to provide for a reserve as set forth in paragraph (f) of this section.

(3)(i) Subject to paragraph (a)(3)(ii) of this section, any amendment or addition to an approved budget must be approved by the Secretary, including shifting of funds from one program, plan, or project to another.

(ii) Shifts of funds which do not cause an increase in the Promotion Board's approved budget and which are consistent with governing bylaws need not have prior approval by the Secretary.

(b) The Promotion Board is authorized to incur such expenses, including provision for a reasonable reserve, as the Secretary finds are reasonable and likely to be incurred by the Promotion Board for its maintenance and functioning, and to enable it to exercise its powers and perform its duties in accordance with the provisions of this subpart. Such expenses shall be paid from funds received by the Promotion Board.

(c) The Promotion Board may accept voluntary contributions, but these shall only be used to pay expenses incurred in the conduct of programs, plans, and projects. Such contributions shall be free from any encumbrance by the donor and the Promotion Board shall retain complete control of their use.

(d) The Promotion Board shall reimburse the Secretary, from funds received by the Promotion Board, for administrative costs incurred by the Secretary in implementing and administering this subpart, including the salaries of Department employees and costs incurred in conducting referenda.

(e) The Promotion Board may establish an operating monetary reserve and may carry over to subsequent fiscal periods excess funds in any reserve so established. Such reserve funds may be

used to defray any expenses authorized under this subpart.

(f) With the approval of the Secretary, the Promotion Board may borrow money for the payment of administrative expenses, subject to the same fiscal, budget, and audit controls as other funds of the Promotion Board. This provision is limited to the first year of operation of the Promotion Board.

§ 1214.51 Assessments.

(a) Any handler initially purchasing, or otherwise placing into interstate, foreign, or intrastate commerce, kiwifruit produced in the United States shall, in the manner as prescribed by the Promotion Board and approved by the Secretary, collect an assessment based upon the number of pounds of kiwifruit marketed in the United States for the account of the producer, and remit the assessment to the Promotion Board.

(b) The rate of assessment effective during any fiscal year shall be the rate specified in the budget for such fiscal year approved by the Secretary, except that:

(1) The rate of assessment shall not exceed $0.10 per seven pound tray of kiwifruit or the equivalent thereof.

(2) The rate of assessment for a fiscal year may be changed at the beginning of the fiscal year only and by regulation as necessary to reflect changed circumstances, except that any such changed rate may not exceed the level of assessment specified in paragraph (b)(1) of this section.

(c) Any person marketing kiwifruit of that person's own production into the channels of commerce in the United States, through retail or wholesale outlets, shall be considered a handler and shall remit to the Promotion Board an assessment on such kiwifruit at the rate then in effect, at such time and in such form and manner prescribed by the Promotion Board, with the approval of the Secretary.

(d)(1) Each importer of kiwifruit shall pay an assessment to the Promotion Board on kiwifruit imported for marketing in the United States, through the U.S. Customs Service. A person acting as a principal or as an agent, broker, or consignee for any person who produces kiwifruit outside the United States shall be considered an importer.

(2) The assessment rate for imported kiwifruit shall be the same or equivalent to the rate provided for kiwifruit produced in the United States.

(3) The import assessment shall be uniformly applied to imported kiwifruit that are identified by the number, 0709.51.0000, in the Harmonized Tariff Schedule of the United States or any other number used to identify fresh kiwifruit.

(4) The assessments due on imported kiwifruit shall be paid when the kiwifruit are entered or withdrawn for consumption in the United States.

(5) Only one assessment shall be paid on each unit of kiwifruit imported.

(e)(1) Each person responsible for remitting assessments under paragraphs (a), (c), or (f) of this section, and importers if the U.S. Customs Service fails to collect the assessment, shall remit the assessments due to the Promotion Board on a monthly basis no later than the fifteenth day of the month following the month in which the kiwifruit were marketed, in such manner as prescribed by the Promotion Board.

(2)(i) The Promotion Board shall impose a late payment charge on any person that fails to remit to the Promotion Board the total amount for which the person is liable on or before the payment due date established under this section. The amount of the late payment charge shall be prescribed in rules and regulations as approved by the Secretary.

(ii) The Promotion Board shall impose an additional charge on any person subject to a late payment charge, in the form of interest on the outstanding portion of any amount for which the person is liable. The rate of interest shall be prescribed in rules and regulations as approved by the Secretary.

(3) Any assessment that is determined to be owing at a date later than the payment due established under this section, due to a person's failure to submit a report to the Promotion Board by the payment due date, shall be considered to have been payable on the payment due date. Under such a situation, paragraphs (e)(2)(i) and (e)(2)(ii) of this section shall be applicable.

(4) Persons failing to remit total assessments due in a timely manner may also be subject to penalties and actions under federal debt collection procedures as set forth in 7 CFR 3.1 through 3.36.

(f) The Promotion Board, with the approval of the Secretary, may enter into agreements authorizing other state mandated organizations to collect assessments in its behalf. Any such organization shall be required to maintain the confidentiality of such information as is required by the Promotion Board for collection purposes. Any reimbursement by the Promotion Board for such services shall be based on reasonable charges for services rendered.

(g) The Promotion Board is hereby authorized to accept advance payment of assessments for the fiscal year by any person, that shall be credited toward any amount for which such person may become liable. The Promotion Board shall not be obligated to pay interest on any advance payment.

(h) Except for the first year of operation of the promotion board, expenses for the administration, maintenance, and functioning of the board may not exceed 30 percent of the budget for a year.

§ 1214.52 Exemption from assessment.

(a) Producers who produce less than 500 pounds of kiwifruit annually shall be exempted from assessment.

(b) Importers who import less than 10,000 pounds of kiwifruit per year shall be exempted from assessment.

(c) Sales of kiwifruit made directly from the producer to a consumer for a purpose other than resale are exempt from assessment.

(d) Domestic and imported kiwifruit used for processing are exempt from assessment. The Promotion Board shall develop a list of approved processors.

(e) To claim an exemption, a producer or importer shall submit an application to the Promotion Board stating the basis on which the person claims the exemption for such year.

(f) If, after a person claims an exemption from assessments for any year under this section, and such person no longer meets the requirements of this paragraph for an exemption, such person shall file a report with the Board in the form and manner prescribed by the Board and pay an assessment on all the kiwifruit produced or imported by such person during the year for which the person claimed the exemption.

(g) Exempted individuals are subject to such safeguards as prescribed in rules and regulations in this part to prevent improper use of this exemption.

§ 1214.53 Influencing governmental action.

No funds received by the Promotion Board under this subpart shall in any manner be used for the purpose of influencing legislation or governmental policy or action, except to develop and recommend to the Secretary amendments to this subpart.

Reports, Books, and Records

§ 1214.60 Reports.

(a) Each producer marketing kiwifruit of that person's own production for resale, and each handler responsible for the collection of assessments under § 1214.51(a) shall be required to report monthly to the Promotion Board, on a form provided by the Promotion Board,

such information as may be required under this subpart or any rules and regulations issued in this part. Such information shall include, but not be limited to, the following:

(1) The handler's name, address, telephone number, and social security number or Employer Identification Number;

(2) Date of report, which is also the date of payment to the Promotion Board;

(3) Period covered by the report; and

(4) The number of kiwifruit containers, weight, size, and type purchased, initially transferred or that in any other manner are subject to the collection of assessments, and a copy of a certificate of exemption, claiming exemption under § 1214.52 from those who claim such exemptions.

(b) If determined necessary by the Promotion Board and approved by the Secretary, each importer shall file with the Promotion Board periodic reports, on a form provided by the Promotion Board, containing at least the following information:

(1) The importer's name, address, telephone number, and social security number or Employer Identification Number;

(2) The quantity of kiwifruit entered or withdrawn for consumption in the United States during the period covered by the report; and

(3) The amount of assessments paid to the U.S. Customs Service at the time of such entry or withdrawal.

(c) For persons who have an exemption from assessments under § 1214.52, such information as deemed necessary by the Board, and approved by the Secretary, concerning the exemption including disposition of exempted kiwifruit.

§ 1214.61 Books and records.

Each person who is subject to this subpart shall maintain and make available for inspection by the Promotion Board staff or the Secretary such books and records as are deemed necessary by the Promotion Board, with the approval of the Secretary, to carry out the provisions of this subpart and any rules and regulations issued in this part, including such books and records as are necessary to verify any reports required. Such books and records shall be retained for at least two years beyond the fiscal year of their applicability.

§ 1214.62 Confidential treatment.

All information obtained from books, records, or reports under the Act, this subpart, and the rules and regulations issued in this part shall be kept confidential by all persons, including all employees and former employees of the Promotion Board, all officers and employees and former officers and employees of contracting and subcontracting agencies or agreeing parties having access to such information. Such information shall not be available to Promotion Board members, producers, importers, exporters, or handlers. Only those persons having a specific need for such information to effectively administer the provisions of this subpart shall have access to such information. Only such information so obtained as the Secretary deems relevant shall be disclosed by them, and then only by judicial order in a suit or administrative hearing brought at the direction, or on the request, of the Secretary, or to which the Secretary or any officer of the United States is a party, and involving this subpart. Nothing in this section shall be deemed to prohibit:

(a) The issuance of general statements based upon the reports of the number of persons subject to this subpart or statistical data collected therefrom, which statements do not identify the information furnished by any person; and

(b) The publication, by direction of the Secretary, of the name of any person who has been adjudged to have violated this subpart, together with a statement of the particular provisions of this subpart violated by such person.

Miscellaneous

§ 1214.70 Right of the Secretary.

All fiscal matters, programs, plans, or projects, rules or regulations, reports, or other substantive actions proposed and prepared by the Promotion Board shall be submitted to the Secretary for approval.

§ 1214.71 Suspension or termination.

(a) Whenever the Secretary finds that this part obstructs or does not tend to effectuate the declared purpose of the Act, the Secretary shall terminate or suspend the operation of provisions of this part.

(b)(1) Six years after the date on which this subpart becomes effective, and at the end of every six-year period thereafter; the Secretary shall conduct a referendum among producers and importers to determine whether they favor continuation, termination, or suspension of this subpart.

(2) The Secretary shall also hold a referendum:

(i) At the request of the Promotion Board; or

(ii) If not less than 30 percent of the kiwifruit producers and importers subject to assessments under the Order submit a petition requesting a referendum be held.

(3) Whenever the Secretary determines that suspension or termination of this subpart is favored by a majority of the kiwifruit producers and importers voting in a referendum under paragraphs (b) (1) or (2) of this section who, during a representative period determined by the Secretary, have been engaged in producing and importing kiwifruit and who, on average, annually produced and imported more than 50 percent of the volume of kiwifruit produced and imported by all those producers and importers voting in the referendum, the Secretary shall:

(i) Suspend or terminate, as appropriate, collection of assessments within six months after making such determination; and

(ii) Suspend or terminate, as appropriate, all activities under this subpart in an orderly manner as soon as practicable.

(4) Referenda conducted under this subpart shall be conducted in such manner as the Secretary may prescribe.

§ 1214.72 Proceedings after termination.

(a) Upon the termination of this subpart, the Promotion Board shall recommend not more than five of its members to the Secretary to serve as trustees for the purpose of liquidating the affairs of the Promotion Board. Such persons, upon designation by the Secretary, shall become trustees for all the funds and property owned, in the possession of, or under the control of the Promotion Board, including any claims unpaid or property not delivered, or any other claim existing at the time of such termination.

(b) The trustees shall:

(1) Continue in such capacity until discharged by the Secretary;

(2) Carry out the obligations of the Promotion Board under any contract or agreement entered into by it under this subpart;

(3) From time to time account for all receipts and disbursements, and deliver all property on hand, together with all books and records of the Promotion Board and of the trustees, to such persons as the Secretary may direct; and

(4) Upon the request of the Secretary, execute such assignments or other instruments necessary or appropriate to vest in such persons full title and right to all of the funds, property, and claims vested in the Promotion Board or the trustees under this subpart.

(c) Any person to whom funds, property, or claims have been transferred or delivered under this subpart shall be subject to the same

obligations imposed upon the Promotion Board and upon the trustees.

(d) Any residual funds not required to defray the necessary expenses of liquidation shall be turned over to the Secretary to be used, to the extent practicable, in the interest of continuing one or more of the promotion, research, consumer information, or industry information programs, plans, or projects authorized under this subpart.

§ 1214.73 Effect of termination or amendment.

Unless otherwise expressly provided by the Secretary, the termination of this subpart or of any rule and regulation issued in this part, or the issuance of any amendment to such provisions, shall not:

(a) Affect or waive any right, duty, obligation, or liability that shall have arisen or may hereafter arise in connection with any provision of this subpart or any such rules or regulations issued in this part;

(b) Release or extinguish any violation of this subpart or any rules or regulations issued in this part; or

(c) Affect or impair any rights or remedies of the United States, the Secretary, or any person with respect to any such violation.

§ 1214.74 Personal liability.

No member or employee of the Promotion Board shall be held personally responsible, either individually or jointly, in any way whatsoever, to any person for errors in judgment, mistakes, or other acts of either commission or omission of such member or employee under this subpart, except for acts of dishonesty or willful misconduct.

§ 1214.75 Patents, copyrights, inventions, publications, and product formulations.

Any patents, copyrights, inventions, publications, or product formulations developed through the use of funds received by the Promotion Board under this subpart shall be the property of the United States Government as represented by the Promotion Board and shall, along with any rents, royalties, residual payments, or other income from the rental, sale, leasing, franchising, or other uses of such patents, copyrights, inventions, publications, or product formulations inure to the benefit of the Promotion Board. Upon termination of certain provisions in this subpart, § 1214.72 shall apply to determine disposition of all such property.

§ 1214.76 Amendments.

Amendments to this subpart may be proposed, from time to time, by the Promotion Board or by any interested person affected by the provisions of the Act, including the Secretary.

§ 1214.77 Separability.

If any provision of this subpart is declared invalid, or the applicability thereof to any person or circumstances is held invalid, the validity of the remainder of this subpart or the applicability thereof to other persons or circumstances shall not be affected thereby.

Subpart B—Rules and Regulations

Definitions

§ 1214.100 Terms defined.

Unless otherwise defined in this subpart, the definitions of terms used in this subpart shall have the same meaning as the definitions in Subpart A—Kiwifruit Research, Promotion, and Consumer Information Order of this part.

Nomination Procedures

§ 1214.110 Nominations.

Nominations shall be made by mail ballot in accordance with the procedures prescribed in § 1214.31. Each mail ballot shall be scheduled so as to ensure that the nominations for each position that will be open at the beginning of the following year are received by the Secretary by May 1, or such other date approved by the Secretary.

§ 1214.111 Mail balloting.

(a) The Promotion Board shall conduct nominations of individuals as candidates for appointment to the Promotion Board by mail nomination form.

(b)(1) Notice of mail balloting to nominate candidates for a position on the Promotion Board shall be publicized by the Promotion Board to producers, importers, kiwifruit exporter organizations and to the Secretary, by March 1 of each year.

(2) Nomination forms will be used to collect names of individuals to be placed on a ballot to be sent to producers and importers to select the individuals for the Secretary's appointment. Completed nomination forms must be returned to the Promotion Board prior to March 30.

(c) Once proposed nominations have been submitted, the Promotion Board shall cause each proposed nomination, if the individual qualifies, to be placed on the producer or importer ballot. The Promotion Board then shall mail a ballot to each known producer or importer.

(d) Each producer or importer shall cast a ballot for each open position on the Promotion Board assigned to the producers or importers/exporters in accordance with the procedures prescribed in § 1214.31. The completed ballot must be returned to the Promotion Board or its designee within 30 days after the ballot is issued.

(e) Within 45 days after a mail ballot is issued, the Promotion Board shall validate the ballots cast, tabulate the votes, and provide the Secretary with the results of the vote and the identification of the top two vote getters for each open position on the Promotion Board.

(f) The Promotion Board shall provide nominees with qualification statements and other specified information. Each nominee selected in the mail ballot will be contacted by the Promotion Board and asked to forward such completed documentation to the Promotion Board within 14 days of such notification.

§ 1214.112 Appointment.

If an employee, partner, officer, or shareholder of a producer, importer or exporter is a current member of the Promotion Board, no nominee who is also an employee, partner, officer, or shareholder of such producer, importer, or exporter shall be appointed to the Promotion Board. A Promotion Board member shall be disqualified from serving on the Promotion Board if such individual ceases to be affiliated with a producer, importer, or exporter the Promotion Board member represents.

General

§ 1214.115 Financial statements.

(a) As requested by the Secretary, the Promotion Board shall prepare and submit financial statements to the Secretary on a periodic basis. Each such financial statement shall include, but not be limited to, a balance sheet, income statement, and expense budget. The expense budget shall show expenditures during the time period covered by the report, year-to-date expenditures, and the unexpended budget.

(b) Each financial statement shall be submitted to the Secretary within 30 days after the end of the time period to which it applies.

(c) The Promotion Board shall submit annually to the Secretary an annual financial statement within 90 days after the end of the fiscal year to which it applies.

Assessments

§ 1214.120 Payment of assessments.

(a) Each handler responsible for collecting assessments on domestic kiwifruit shall collect the amounts

assessed and remit such amounts to the Promotion Board on a monthly basis not later than the fifteenth day of the month following the month in which the kiwifruit were marketed to or through the handler, whatever comes first.

(b) A state mandated organization may collect producer assessments from handlers then remit the funds to the Promotion Board on a monthly basis. The state mandated program collecting the assessments must provide access to records for the purpose of periodic audit.

(c) Each producer who is also a handler responsible for paying any assessment amount on the producer's own kiwifruit shall complete a shipment data form to the Promotion Board not later than the fifteenth day of the month following the month in which the kiwifruit were marketed by the producer. An invoice will be sent to the producer for the amount owed.

(d) Each importer shall be responsible for remittance to the Promotion Board of any assessment amount not collected by the U.S. Customs Service at the time of entry or withdrawal for consumption into the United States. Any such assessment amount shall be remitted to the Promotion Board on a monthly basis not later than the fifteenth day of the month following the month of entry or withdrawal for consumption into the United States. Any person who imports kiwifruit, as principal or as an agent, broker, or consignee for any person who produces kiwifruit outside the United States shall be considered an importer.

(e) Remittance shall be by check, draft, or money order payable to the National Kiwifruit Board or Kiwifruit Promotion Board, and shall be accompanied by a report, on a form provided by the Promotion Board.

(f) The Promotion Board shall impose a late payment charge on any handler or importer who fails to make timely remittance to the Promotion Board of the total assessment amount for which the person is liable. Such late payment charge shall be imposed on any assessments not received by the last day of the month following the month in which the kiwifruit involved were marketed or, in the case of imports, not collected by the U.S. Customs Service at the time of entry or withdrawal for consumption into the United States. This one-time late payment charge shall be 10 percent of the assessments due before interest charges have accrued. The late payment charge will not be applied to any late payments postmarked within 15 days after the end of the month such assessments are due.

(g) In addition to the late payment charge, the Promotion Board shall charge interest at a rate of 1.5 percent per month on the outstanding balance, including the late payment charge and any accrued interest, of any account that remains delinquent beyond the last day of the second month following the month the Kiwifruit involved were marketed. However, handlers paying their assessments, in accordance with paragraph (i) of this section, will not be subject to the 1.5 percent per month interest under this paragraph until the last day of the second month after such assessments were due under paragraph (i) of this section. In the case of imports, such a rate of interest will be charged to any account that remains delinquent on any assessments not collected by the U.S. Customs Service at the time of entry or withdrawal for consumption into the United States. Such a rate of interest will continue to be charged monthly until the outstanding balance is paid to the Promotion Board.

(h) Any assessment determined by the Promotion Board at a date later than prescribed by this section, because of a person's failure to submit a report to the Promotion Board when due, shall be considered to have been payable by the date it would have been due if the report had been filed on time. A late payment charge and monthly interest charges on the outstanding balance shall be applicable to such unpaid assessment in accordance with paragraphs (f) and (g) of this section.

(i) In lieu of the monthly assessment payment and reporting requirements of §§ 1214.125 and 1214.60, the Promotion Board may permit a handler to make advance payment of the total estimated assessment amount due to the Promotion Board for the ensuing fiscal year, or portion thereof, prior to the actual determination of assessable kiwifruit.

(j) Any person whose prepayment exceeds the amount paid shall be reimbursed for the amount of overpayment. The Promotion Board shall not, in any case, be obligated to pay interest on any advance payment.

§ 1214.121 Exemption procedures.

(a) Any producer who produces less than 500 pounds of kiwifruit annually or who produces kiwifruit for processing and who desires to claim an exemption from assessments during a fiscal year as provided in § 1214.52 shall apply to the Promotion Board, on a form provided by the Promotion Board, for a certificate of exemption. Such producer shall certify that their production of kiwifruit shall be less than 500 pounds, for the fiscal year for which the exemption is claimed. Any importer who imports less than 10,000 pounds of kiwifruit annually or who imports kiwifruit for processing and who desires to claim an exemption from assessments during a fiscal year as provided in § 1214.52 shall apply to the Promotion Board, on a form provided by the Promotion Board, for a certificate of exemption. Such importer shall certify that their importation of kiwifruit shall not exceed 10,000 pounds, for the fiscal year for which the exemption is claimed.

(b) On receipt of an application, the Promotion Board shall determine whether an exemption may be granted. The Promotion Board then will issue, if deemed appropriate, a certificate of exemption to each person that is eligible to receive one. Each person who is exempt from assessment must provide an exemption number to the first handler in order not to be subject to collection of an assessment on kiwifruit. Handlers and importers, except as otherwise authorized by the Promotion Board, shall maintain records showing the exemptee's name and address along with the exemption number assigned by the Promotion Board.

(c) Importers who are exempt from assessment shall be eligible for reimbursement of assessments collected by the U.S. Customs Service and shall apply to the Promotion Board for reimbursement of such assessments paid. No interest will be paid on assessments collected by the U.S. Customs Service and determined to be exempt at a later time. Requests for reimbursement shall be submitted to the Board within 90 days of the last day of the year the kiwifruit were actually imported.

(d) Any person who desires to renew the exemption from assessments for a subsequent fiscal year shall reapply to the Promotion Board, on a form provided by the Promotion Board, for a certificate of exemption.

(e) The Promotion Board may require persons receiving an exemption from assessments to provide to the Promotion Board reports on the disposition of exempt kiwifruit and, in the case of importers, proof of payment of assessments.

Reports

§ 1214.125 Reports.

Each handler or producer that is also a handler shall be required to report monthly to the Promotion Board such information as may be required under § 1214.60. In addition, each handler may be required to provide the farm identification number or social security number of each producer the handler

has dealt with during the time period covered by the report.

Miscellaneous

§ 1214.130 OMB control numbers.

The control number assigned to the information collection requirements by the Office of Management and Budget pursuant to the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35, is OMB control number 0581–0093, except for the Promotion Board nominee background statement form which is assigned OMB control number 0505–0001.

Dated: October 8, 1997.

Lon Hatamiya,

Administrator, Agricultural Marketing Service.

[FR Doc. 97–27322 Filed 10–16–97; 8:45 am]

BILLING CODE 3410–02–U

Federal Register

Friday
October 17, 1997

Part IV

The President

Proclamation 7041—International Rural Women's Day, 1997

Federal Register
Vol. 62, No. 201
Friday, October 17, 1997

Presidential Documents

Title 3—

The President

Proclamation 7041 of October 15, 1997

International Rural Women's Day, 1997

By the President of the United States of America

A Proclamation

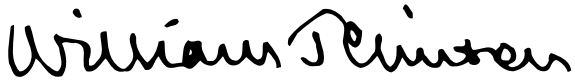
Our world has been continually uplifted and renewed by the contributions of women. Women of courage and conscience, women of strength and compassion, women of vision and talent have enriched every aspect of international society. In our own Nation, the names of such extraordinary individuals as Harriet Tubman, Susan B. Anthony, Jane Addams, Rosa Parks, Dolores Huerta, and so many more, are etched on our history and in our hearts. But there are millions of other women who live and work among us whose names will never be known, but whose efforts and energy contribute profoundly to the quality of our lives. Rural women are numbered among these many quiet heroes.

Today rural women comprise more than one-quarter of the world's population, and they form the basis of much of the world's agricultural economy. In the United States, working on farms and ranches, they play a vital part in ensuring a healthy, safe, and abundant supply of food and fiber for our people. In developing countries, as small farmers, laborers, and entrepreneurs, rural women help produce most of the food, create many of the jobs, and manage most of their countries' natural resources. While millions of rural women worldwide live below the poverty level, struggling to survive with scarce resources and little training and education, they still manage to feed their families and contribute to their communities.

When the international community came together in Beijing in 1995 for the Fourth United Nations World Conference on Women, rural women made their voices heard by world leaders, and their hard work and sacrifice were at last recognized by people across the globe. Next year, when the United States hosts the Second World Conference on Women in Agriculture, we will continue to focus on the status of rural women and their contributions to our world.

NOW, THEREFORE, I, WILLIAM J. CLINTON, President of the United States of America, by virtue of the authority vested in me by the Constitution and laws of the United States, do hereby proclaim October 15, 1997, as International Rural Women's Day in the United States. I call upon the American people to observe this day with appropriate programs and activities in recognition of the extraordinary contributions rural women make to the quality of our lives, both in America and around the world.

IN WITNESS WHEREOF, I have hereunto set my hand this fifteenth day of October, in the year of our Lord nineteen hundred and ninety-seven, and of the Independence of the United States of America the two hundred and twenty-second.



[FR Doc. 97–27814
Filed 10–16–97; 11:12 am]
Billing code 3195–01–P

Friday
October 17, 1997

Part V

Office of Management and Budget

Cancellation Pursuant to Line Item Veto Act; Treasury and General Government Appropriations Act, 1998; Notices

OFFICE OF MANAGEMENT AND BUDGET

Cancellation Pursuant to Line Item Veto Act; Treasury and General Government Appropriations Act, 1998

October 16, 1997.

One Special Message from the President under the Line Item Veto Act is published below. The President signed this message on October 16, 1997. Under the Act, the message is required to be printed in the **Federal Register** (2 U.S.C. 691a(c)(2)).

Clarence C. Crawford,

Associate Director for Administration.

THE WHITE HOUSE
Washington,
October 16, 1997.

Dear Mr. Speaker:

In accordance with the Line Item Veto Act, I hereby cancel the dollar amount of discretionary budget authority, as specified in the attached report, contained in the ''Treasury and General Government Appropriations Act, 1998'' (Public Law 105–61; H.R. 2378). I have determined that the cancellation of this amount will reduce the Federal budget deficit, will not impair any essential Government functions, and will not harm the national interest. This letter, together with its attachment, constitutes a special message under section 1022 of the Congressional Budget and Impoundment Control Act of 1974, as amended.

Sincerely,

William J. Clinton.

The Honorable Newt Gingrich,
Speaker of the House of Representatives, Washington, D.C. 20515.

THE WHITE HOUSE
Washington,
October 16, 1997.

Dear Mr. President:

In accordance with the Line Item Veto Act, I hereby cancel the dollar amount of discretionary budget authority, as specified in the attached report, contained in the ''Treasury and General Government Appropriations Act, 1998'' (Public Law 105–61; H.R. 2378). I have determined that the cancellation of this amount will reduce the Federal budget deficit, will not impair any essential Government functions, and will not harm the national interest. This letter, together with its attachment, constitutes a special message under section 1022 of the Congressional Budget and Impoundment Control Act of 1974, as amended.

Sincerely,

William J. Clinton.

The Honorable Albert Gore, Jr.,
President of the Senate, Washington, D.C. 20510.

Cancellation No. 97–56

CANCELLATION OF DOLLAR AMOUNT OF DISCRETIONARY BUDGET AUTHORITY

Report Pursuant to the Line Item Veto Act, P.L. 104–130

Bill Citation: ''Treasury and General Government Appropriations Act, 1998'' (H.R. 2378).

1(A). Dollar Amount of Discretionary Budget Authority: $8,000 thousand in FY 1998, $183,000 thousand in FY 1999, $209,000 thousand in FY 2000, $221,000 thousand in FY 2001, and $233,000 thousand in FY 2002 due to reductions in employee contributions to the Civil Service Retirement and Disability Fund (CSRDF). These reduced contributions would result from employee elections to switch retirement coverage to the Federal Employees Retirement System (FERS) from enrollment in the Civil Service Retirement System (CSRS) that is authorized by Section 642.

1(B). Determinations: This cancellation will reduce the Federal budget deficit, will not impair any essential Government functions, and will not harm the national interest.

1(C), (E). Reasons for Cancellation; Facts, Circumstances, and Considerations Relating to or Bearing Upon the Cancellation; and Estimated Effect of Cancellation on Objects, Purposes, and Programs: Section 642 would require the Office of Personnel Management to conduct an Open Season to permit Federal employees to switch enrollment from CSRS to FERS between July 1, 1998 and December 31, 1998. The estimated impact is the net reduction in employee contributions to the CSRDF trust fund from 7 percent of pay under CSRS to 0.8 percent under FERS. It is estimated that 5 percent of CSRS-covered employees would switch. This provision is being canceled because: (1) it would require the employing agencies to absorb increased retirement costs, using funds that otherwise would be available for payroll and other agency needs; (2) it would inhibit agency downsizing and restructuring efforts by discouraging voluntary turnover; (3) it was not requested in the President's FY 1998 budget; and (4) it was not the subject of extensive deliberation and debate prior to enactment.

1(D). Estimated Fiscal, Economic, and Budgetary Effect of Cancellation: As a result of the cancellation, Federal receipts will not decrease, as specified below. This will have a commensurate effect on the Federal budget deficit and, to that extent, will have a beneficial effect on the economy.

Receipt changes

[In thousands of dollars]

Fiscal year:	
1998	−8,000
1999	−183,000
2000	−209,000
2001	−221,000
2002	−233,000
Total	−854,000

1(F). Adjustments to Non-Defense Discretionary Spending Limits

Budget authority: The estimated budget authority effect for each year is equal to the receipt changes shown above.

Outlays: The estimated outlay effect for each year is equal to the receipt changes shown above.

Evaluation of Effects of These Adjustments upon Sequestration Procedures: If a sequestration were required, such sequestration would occur at levels that are reduced by the amounts above.

2(A). Agency: Office of Personnel Management.

2(A). Bureau: None.

2(A). Governmental Function/Project (Account): Civil Service retirement (Civil Service Retirement and Disability Fund).

2(B). States and Congressional Districts Affected: All.

2(C). Total Number of Cancellations (inclusive) in Current Session in each State and District identified above: The provision would have had a national effect.

[FR Doc. 97–27914 Filed 10–16–97; 4:12 pm]
BILLING CODE 3110–01–P

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Vol. 62, No. 201

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