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Rules and Regulations

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This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

The Code of Federal Regulations is sold by the Superintendent of Documents. Prices of new books are listed in the first FEDERAL REGISTER issue of each week.

OFFICE OF PERSONNEL MANAGEMENT

5 CFR Part 890

RIN 3206–AK04

Changes in Health Benefits Enrollment

AGENCY: Office of Personnel Management.

ACTION: Final rule.

SUMMARY: The Office of Personnel Management (OPM) is issuing final regulations on changes in health benefits enrollment for annuitants or survivor annuitants when a carrier terminates participation in the Federal Employees Health Benefits (FEHB) Program. We are amending the regulations to give OPM the authority to enroll annuitants in whichever option of the Blue Cross Blue Shield (BC/BS) Service Benefit Plan it determines will most closely approximate the terminated plan.

EFFECTIVE DATE: July 11, 2005.

FOR FURTHER INFORMATION CONTACT: Nataya Battle, (202) 606–1874, or e-mail to *nataya.battle@opm.gov.*

SUPPLEMENTARY INFORMATION:

Background

On February 9, 2004, OPM published proposed regulations in the **Federal Register** (69 FR 5935–5936) on changes in health benefits enrollment for annuitants or survivor annuitants when a carrier terminates participation in the FEHB Program. Effective August 18, 1997, OPM amended 5 CFR 890.306(l)(4) to authorize OPM to enroll an annuitant in the standard option of the Service Benefit Plan when the annuitants' health plan terminates participation in whole or in part in the FEHB Program and the annuitant fails to elect to change to another participating health plan. At that time, the BC/BS Service Benefit Plan offered the high option and the standard option. The standard option was the lower level of benefits with a lower premium cost. Beginning with the January 1, 2002, contract year, the BC/BS Service Benefit Plan merged the high option coverage into the standard option coverage and added a basic option. The standard option is now the highest level of coverage offered with the more costly premium rate.

In the existing regulation, an annuitant who does not elect to change health plans is deemed to have enrolled in the standard option, or if the plan he or she was enrolled in had two options, he or she is deemed to have enrolled in the same option previously enrolled in (either high or low), if the annuity is sufficient to pay the high option premium. The annuitant may not change to another health plan until the next open season.

The more costly premium rate may not be affordable for many annuitants. Amending this regulation will allow OPM the flexibility to consider the premium rate and the benefits that the annuitant was receiving under his or her terminated health plan, and enroll the annuitant in the option of the BC/BS Service Benefit Plan that most closely approximates the terminated plan. In addition, this amendment will give the annuitant the opportunity to change the option or to change to another health plan of his or her choice retroactively within 90 days of the date OPM sent notification that he or she has been deemed enrolled in a particular option of the BC/BS Service Benefit Plan.

On February 9, 2004, OPM issued proposed regulations at 69 FR 5935–5936 and requested comments by April 9, 2004. OPM received comments from NARFE. NARFE contends that the benefit structure of the BC/BS Service Benefit Plan basic option is not suitable for annuitants who have Medicare because the basic option does not have a mail service prescription drug benefit and co-payments are based on a supply of up to 34-days as opposed to a 90-day supply under the standard option. In addition, NARFE contends that the basic option does not have a skilled nursing facility benefit in conjunction with Medicare, as does the standard option. OPM's response to these contentions is that annuitants who are deemed enrolled in the BC/BS Service Benefit Plan basic option will have been previously enrolled in a health plan that is similar to the basic option. NARFE also requests that annuitants be allowed up to 90-days to elect to enroll in a new health plan. OPM has agreed to amend the regulation to allow all annuitants up to 90-days to elect to enroll in a new plan to accommodate the annuitants who do not realize that there has been a change in the amount of their health insurance premiums until they receive their February annuity check.

Regulatory Flexibility Act

OPM has determined that this regulation will not have a significant economic impact on a substantial number of small entities because the regulation will only affect health benefits of certain Federal retirees.

Executive Order 12866, Regulatory Review

This rule has been reviewed by the Office of Management and Budget in accordance with Executive Order 12866.

Federalism

We have examined this rule in accordance with Executive Order 13132, Federalism, and have determined that this rule will not have any negative impact on the rights, roles, and responsibilities of State, local, or tribal governments.

List of Subjects in 5 CFR Part 890

Administrative practice and procedure, Government employees, Health Facilities, Health insurance, Health professions, Hostages, Iraq, Kuwait, Lebanon, Military personnel, Reporting and recordkeeping requirements, Retirement.

U.S. Office of Personnel Management.

Dan G. Blair,

Acting Director.

■ Accordingly, OPM is amending 5 CFR part 890 as follows:

PART 890—FEDERAL EMPLOYEES HEALTH BENEFITS PROGRAM

■ 1. The authority citation for part 890 is revised to read as follows:

Authority: 5 U.S.C. 8913; 890.303 also issued under 50 U.S.C. 403p, 22 U.S.C. 4069c and 4069c–1; subpart L also issued under sec. 599C of Pub. L. 101–513, 104 Stat. 2064, as amended; § 890.102 also issued under sections 11202(f), 11232(e), 11246(b) and (c) of Pub. L. 105–33, 111 Stat. 251; and section

721 of Pub. L. 105–261, 112 Stat. 2061 unless otherwise noted.

■ 2. In § 890.306 revise paragraphs (l)(4)(ii), (iii), and (iv) and (q)(1)(ii) to read as follows:

§ 890.306 When can annuitants or survivor annuitants change enrollment or reenroll and what are the effective dates?

* * * * *

(l) * * *

(4) * * *

(ii) If a plan discontinues all of its existing options, an annuitant who does not change his or her enrollment is deemed to have enrolled in the option of the Blue Cross and Blue Shield Service Benefit Plan that OPM determines most closely approximates the terminated plan, except when the annuity is insufficient to pay the withholdings, then paragraph (q) of this section applies.

(iii) If a plan has two options, and one option of the plan is discontinued, an annuitant who does not change the enrollment is considered to be enrolled in the remaining option of the plan, except when the annuity is insufficient to pay the withholdings, then paragraph (q) of this section applies.

(iv) After an involuntary enrollment under paragraph (l)(4)(ii) or (iii) of this section becomes effective, the annuitant may change the enrollment to the other option of the Blue Cross and Blue Shield Service Benefit Plan or to another health plan of his or her choice retroactively within 90-days after OPM advises the annuitant of the new enrollment;

* * * * *

(q) * * *

(1) * * *

(ii) Enroll in any plan in which the annuitant's share of the premium is less than the amount of annuity. If the annuitant elects to change to a lower cost enrollment, the change takes effect immediately upon loss of coverage under the prior enrollment. The exemptions from debt collection procedures that are provided under § 831.1305(d)(2) and § 845.205(d)(2) of this chapter apply to elections under this paragraph (q)(1)(ii).

* * * * *

[FR Doc. 05–11578 Filed 6–9–05; 8:45 am]

BILLING CODE 6325–39–P

DEPARTMENT OF AGRICULTURE

Commodity Credit Corporation

7 CFR Part 1421

RIN 0560–AH20

Designated Marketing Associations for Peanuts

AGENCY: Commodity Credit Corporation, USDA.

ACTION: Final rule.

SUMMARY: This rule sets out regulations governing the use of designated marketing associations in connection with the making of marketing assistance loans for peanuts and the making of loan deficiency payments in lieu of such loans. These regulations reflect current procedures under broader regulations that precede this rule and specify when storage credit begins for loans handled by designated marketing associations.

DATES: Effective June 10, 2005.

FOR FURTHER INFORMATION CONTACT: Chris Kyer, Program Manager, Price Support Division, FSA/USDA, STOP 0512, 1400 Independence Ave. SW., Washington, DC 20250–0512; telephone (202) 720–7935; facsimile (202) 690–3307; e-mail: *chris.kyer@wdc.usda.gov.* Persons with disabilities who require alternative means of communication (Braille, large print, audio tape, etc.) should contact the USDA Target Center at (202) 720–2600 (voice and TDD).

SUPPLEMENTARY INFORMATION:

Background

This rule sets out regulations governing the use of ''designated marketing associations'' (DMA's) by peanut producers in connection with the Farm Security and Rural Investment Act of 2002, Public Law 107–171, (''2002 Act''), in the making of marketing assistance loans (MAL's) and loan deficiency payments (LDP's) in lieu of MAL's. Section 1307(a)(4) of the 2002 Act provided for peanuts that such loans and LDP's could be obtained through a DMA or a marketing cooperative of producers approved by the Secretary, or the Farm Service Agency of the Department. Regulations governing such loans and LDP's are codified in 7 CFR Part 1421 and include DMA provisions. Rules relating to the use of cooperative marketing associations (CMA's) are found at 7 CFR Part 1425. This rule adds greater specificity to part 1421's DMA provisions consistent with current procedures and reorganizes part 1421 by designating a separate subpart for the DMA provisions. Also, the rule specifies when storage credit may begin for DMA-handled loans. Also, § 1421.115 is renumbered as 1421.114 to reflect that the latter number was not being used. Further, the authority citation for Part 1421 is updated.

Notice and Comment

Section 1601(c) of the Farm Security and Rural Investment Act of 2002 (2002 Act) provides that the administration of Title I of the 2002 Act shall be made without regard to the notice and comment provisions of 5 U.S.C. 553 or the Statement of Policy of the Secretary of Agriculture effective July 24, 1971, (36 FR 13804) relating to notices of proposed rulemaking and public participation in rulemaking. Likewise, Section 1601 of the 2002 Act provides that in carrying out the provisions exempting the administration of the program from notice and comment, the Secretary shall use the authority provided under 5 U.S.C. section 808 of Title 5, United States Code. Under the latter provisions, certain rules are exempted from possible Congressional review before implementation where it is determined that going without notice and public procedures are in the public interest. Such is the case here, in light of the explicit provisions of Section 1601. In addition, this rule simply sets out procedures for voluntary participation by non-producers related to an ongoing program and the new regulations reflect current policy. For those reasons as well, delay in implementation would be contrary to the public interest. Accordingly, this rule is made effective on publication.

Executive Order 12866

This rule has been designated as ''Not Significant'' under Executive Order 12866, and has not been reviewed by the Office of Management and Budget.

Federal Assistance Programs

The title and number of the Federal assistance program in the Catalog of Federal Domestic Assistance to which this final rule applies is 10.051—Commodity Loans and Loan Deficiency Payments.

Regulatory Flexibility Act

The Regulatory Flexibility Act is not applicable to this rule because the Office of the Secretary, FSA and CCC are not required by 5 U.S.C. 553 or any other law to publish a notice of proposed rulemaking for the subject matter of this rule.

Environmental Assessment

The environmental impacts of this rule have been considered consistent

with the National Environmental Policy Act of 1969 (NEPA), 42 U.S.C. 4321 *et seq.*, the regulations of the Council on Environmental Quality (40 CFR parts 1500–1508), and regulations of the Farm Service Agency (FSA) of the Department of Agriculture (USDA) regarding compliance with NEPA, 7 CFR part 799. An environmental evaluation was completed and the action has been determined not to have the potential to significantly impact the quality of the human environment and no environmental assessment or environmental impact statement is necessary. A copy of the environmental evaluation is available for inspection and review upon request.

Executive Order 12778

The final rule has been reviewed under Executive Order 12778. This rule preempts State laws that are inconsistent with its provisions. This rule is not retroactive. Before any judicial action may be brought regarding this rule, all administrative remedies must be exhausted.

Executive Order 12372

This program is not subject to Executive Order 12372, which requires 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

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) does not apply to this rule because the Office of the Secretary, FSA and CCC are not required by 5 U.S.C. 553 or any other law to publish a notice of proposed rulemaking about the subject matter of this rule. Further, this rule imposes no unfunded mandates, as defined in UMRA, on any local, State, or tribal government or the private sector.

Paperwork Reduction Act

Section 1601(c) of the 2002 Act provides that the promulgation of regulations and the administration of Title I of the 2002 Act shall be made without regard to chapter 5 of title 44 of the United States Code (the Paperwork Reduction Act). Accordingly, these regulations and the forms, and other information collection activities needed to administer the program authorized by these regulations, are not subject to review by the Office of Management and Budget under the Paperwork Reduction Act.

Government Paperwork Elimination Act

FSA is committed to compliance with the Government Paperwork Elimination Act (GPEA) and the Freedom to E-File Act, which require Government agencies in general, and FSA in particular, to provide the public the option of submitting information or transacting business electronically to the maximum extent possible. The forms and other information collection activities required for participation in the program are not yet fully implemented for the public to conduct business with FSA electronically. Currently, however, loan application forms are available electronically through the USDA eForms Web site for downloading. Applications from producers may be submitted to current DMA, by mail or by FAX if appropriate FAX authorization forms are on file. At this time, electronic submission of forms is also available and producers, or DMA's acting on their behalf, may also file for e-LDP's on line.

List of Subjects in 7 CFR Part 1421

Loan programs—agriculture, Peanuts.

■ For the reasons set out in the preamble, 7 CFR part 1421 is amended as set forth below.

PART 1421—GRAINS AND SIMILARLY HANDLED COMMODITIES—MARKETING ASSISTANCE LOANS AND LOAN DEFICIENCY PAYMENTS FOR THE 2002 THROUGH 2007 CROP YEARS

■ 1. The authority citation for 7 CFR part 1421 is revised to read as follows:

Authority: 7 U.S.C. 7931 *et seq.*; 15 U.S.C. 714b, 714c.

■ 2. In § 1421.3, the definition of ''Designated marketing association'' is revised to read as follows:

§ 1421.3 Definitions.

* * * * *

Designated Marketing Association (DMA) means an entity, or a subsidiary thereof, that performs marketing functions for peanut producers and is designated to handle marketing assistance loans and loan deficiency payments for them. A DMA is eligible to perform those functions only if the DMA meets the eligibility criteria set out elsewhere in this part.

* * * * *

§ 1421.115 [Redesignated]

■ 3. Section 1421.115 is redesignated as § 1421.114.

Subpart E—[Redesignated]

■ 4. Redesignate subpart E, §§ 1421.5551 through 1421.5559, as subpart F and add a new subpart E as follows:

Subpart E—Designated Marketing Associations for Peanuts

Sec.

1421.400 Applicability and abbreviations.
1421.401 Definitions.
1421.402 DMA responsibilities.
1421.403 DMA eligibility to process loans and loan deficiency payments.
1421.404 DMA approval.
1421.405 Financial security.
1421.406 Liability.
1421.407 Reporting requirements.
1421.408 Suspension and termination.
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1421.410 Monitoring payment limitations.
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1421.412 Forms.
1421.413 Powers of attorney.
1421.414 Liens and waivers.
1421.415 Producer request to a DMA for an MAL or LDP.
1421.416 Processing marketing assistance loans.
1421.417 Processing loan deficiency payments.
1421.418 Disbursing MAL and LDP proceeds.
1421.419 Date storage credit begins on DMA-handled loans.
1421.420 Submitting MAL and LDP documentation to FSA.
1421.421 MAL or LDP servicing.
1421.422 Inspections and reviews.
1421.423 Appeals.

§ 1421.400 Applicability and abbreviations.

(a) This subpart sets forth the terms and conditions under which an entity which is a marketing association of peanut producers, or a subsidiary of such an entity, may qualify to become an eligible ''designated marketing association'' or ''DMA'' qualified to process peanut marketing assistance loans and peanut loan deficiency payments for peanut producers. This subpart only applies with respect to peanut loans and peanut loan deficiency payments. This subpart also specifies when storage credit will begin with respect to peanuts under loans handled by designated marketing associations.

(b) In addition to other abbreviations that may be used, the following abbreviations apply to this subpart:

(1) *CCC* means the Commodity Credit Corporation.

(2) *CMA* means cooperative marketing associations which are the subject of regulations in part 1425 of this chapter.

(3) *DMA* means designated marketing associations.

(4) *EWR* means electronic warehouse receipts.

(5) *FSA* means the Farm Service Agency of the U.S. Department of Agriculture.

(6) *LDP* means loan deficiency payments as provided for in this part.

(7) *MAL* means marketing assistance loans as provided in this part.

§ 1421.401 Definitions.

The definitions set forth in this section shall apply for purposes of program administration under this subpart. The terms defined in this part, in part 718 of this title, and in parts 1425 and 1427 of this chapter shall also be applicable, except where those definitions conflict with the definitions in this section.

Administrative County Office is the FSA County Office where a producer's FSA records are maintained.

Control or Recording FSA County Office is the FSA County Office that controls subsidiary files for producers designated as multi-county producers.

Current net worth ratio means current assets minus current liabilities, divided by current liabilities, based on the financial statement provided in connection with a DMA application or a recertification for DMA status.

DMA Service County Office is an FSA County Office designated by CCC to accept, process, and disburse bundled peanut MAL's and LDP's to a DMA. In the absence of a centralized MAL and LDP processing system for peanuts, a service county FSA office is necessary for entering MAL's and LDP's made by DMA's into CCC accounting systems.

Drawdown account is an account titled to the DMA at a financial institution and funded at the discretion of CCC for the purpose of allowing the DMA to advance funds to producers who have applied for MAL's and LDP's before a subsequent MAL or LDP is made to the DMA by an assigned FSA county office.

Electronic warehouse receipt or EWR means a receipt electronically filed in a central filing system by an approved provider as provided in an executed, ''Farm Service Agency Provider Agreement to Electronically File and Maintain Warehouse Receipts.''

Security means a certified or cashier's check payable to CCC, an irrevocable commercial letter of credit in a form acceptable to CCC, a performance or surety bond conditioned on the DMA fully discharging all of its obligations under this part, or other form of security as CCC may deem appropriate.

§ 1421.402 DMA responsibilities.

(a) DMA's are eligible to process the marketing loans and loan deficiency payments provided for in this part only for peanut producers and only if the DMA and the producers and peanuts meet all eligibility criteria set out in this part, including, but not limited to, the DMA eligibility provisions of this subpart. In carrying out those functions, DMA's must:

(1) Prepare and execute the appropriate CCC peanut MAL and LDP application documents;

(2) Determine whether producers and the commodity are eligible for MAL's and LDP's, including whether the otherwise eligible peanuts are free and clear of all liens which DMA's shall determine by performing lien searches at DMA's expense;

(3) Instruct the holder of EWR's, if applicable, to notify the EWR provider to amend the EWR to show CCC is the holder;

(4) Receive MAL and LDP documents from a DMA Service County Office;

(5) Disburse peanut MAL's and LDP proceeds to eligible producers;

(6) Prepare and execute documents for MAL repayments;

(7) Collect loan repayments from producers or buyers and transmitting these funds to CCC;

(8) Transmit documents to render forfeited collateral to CCC; and

(9) Collect data for reporting to CCC as required by CCC;

(b) As part of performing the responsibilities in paragraph (a) of this section, DMA's shall:

(1) Become knowledgeable of and follow the procedures in CCC and FSA peanut program regulations, applicable notices published in the **Federal Register**, applicable FSA peanut program handbooks and amendments thereto, and any applicable notices or instructions issued by FSA and the Agricultural Marketing Service.

(2) Make and service CCC peanut MAL's and LDP's, only upon the presenting by producers or their agents of the warehouse receipts, unless otherwise directed by CCC.

(3) Attend, at the DMA's expense, DMA peanut MAL, and LDP program training offered by CCC.

(4) Provide sufficient personnel, computer hardware, computer communications systems, and software, as determined necessary by CCC, to administer the peanut MAL and LDP program.

§ 1421.403 DMA eligibility to process loans and loan deficiency payments.

(a) A DMA is eligible to process any marketing assistance loan or loan deficiency payments only if approved in advance to handle such matters by the Farm Service Agency pursuant to this part; and:

(1) The DMA meets the financial requirements and other requirements in this subpart and part;

(2) The DMA is comprised solely of peanut producers or is a subsidiary of an organization of peanut producers;

(3) The DMA is not controlled directly or indirectly by a person or entity that acquires peanuts for processing or crushing through a business involved in buying and selling peanuts or peanut products;

(4) The DMA does not take title at any time to any peanuts for which it processes loans or loan deficiency payments, irrespective of whether such title is taken before or after those activities are performed. If such title or interest is taken, the DMA shall be responsible to return to CCC the full amount of the CCC proceeds disbursed with respect to the peanuts; and

(5) The DMA meets any additional requirements imposed by CCC or FSA.

(b) The DMA's activities under this part shall be conducted only with respect to peanuts and only for producers and peanuts that meet all the eligibility requirements of this part. Such requirements include, but are not limited to, the requirement of § 1421.6 that the producer must have the beneficial interest in the peanuts while the peanuts are under loan or when the loan deficiency payment is received and must be the only person that has had such an interest in the peanuts prior to that time except as allowed by § 1421.6.

§ 1421.404 DMA approval.

(a) Entities wishing to apply to be a DMA enabled to perform loan and loan deficiency functions under this part for peanuts must submit an application for such approval to FSA in a form approved by CCC. That application shall include the following:

(1) Two originals of a properly executed Designated Marketing Association agreement containing the terms and conditions prescribed by CCC.

(2) A financial statement of not less than 1 year old on the date submitted, including accompanying notes, schedules, or exhibits, certified by a certified public accountant as fairly representing the entity's financial condition.

(3) The entity's tax identification number.

(4) A copy of any applicable incorporating or partnership documents.

(5) The applicant entity's mailing address, electronic mail address, and telephone number and facsimile number.

(6) Any and all information requested by CCC regarding the DMA's materials,

and equipment as CCC determines is necessary for the applicant to perform the services for which the approval to perform is sought.

(7) A narrative explaining how the proposed DMA entity or parent entity provides marketing services to peanut producers.

(8) Any additional information or financial security requested by the Agency.

(b) Applicants are responsible for notifying FSA when any changes occur to their operations requiring amendments to their application or supporting documents.

§ 1421.405 Financial security.

In order to be approved to handle loans and loan deficiency payments, the DMA must:

(a) Have a current net worth ratio of at least 1:1.

(b) Provide security equal to $100,000 or a greater amount as determined by CCC.

§ 1421.406 Liability.

(a) DMA's shall indemnify CCC against any claim or loss by CCC in connection with the processing of any MAL's or LDP's or other activity carried out by the DMA. If CCC pays any claim or suffers a loss as a result of the actions of DMA, or if a refund otherwise becomes due to CCC, payment in the amount of such losses or refund, plus interest, may be set-off by CCC from the financial security provided by DMA as required by this subpart. If the amount of the loss exceeds the amount of the financial security, such amount shall be paid to CCC by DMA with interest. Interest and other charges may be assessed consistent with § 1403.9 of this chapter. Remedies provided in this section or part are in addition to other remedies or penalties, whether civil, criminal or otherwise, as may apply.

(b) If a DMA becomes liable to CCC under paragraph (a) of this section or otherwise in connection with this subpart, such DMA shall not be eligible to process a LDP or MAL until the claim amount owed CCC is paid in full, and the full amount of financial security required by this subpart has been restored.

§ 1421.407 Reporting requirements.

(a) *Report of changes.* A DMA shall furnish information to CCC within thirty calendar days relating to any substantial change in the DMA operations including but not limited to the following:

(1) A change in its articles of incorporation;

(2) A resolution affecting loan or LDP operations.

(3) A change to the DMA's name, address, phone number, or related information on the DMA agreement.

(b) *Other Information.* The DMA shall supply such additional information as CCC may request related to the DMA's continued approval by CCC to process loans and LDP's under the authority provided in this subpart.

(c) *CCC request for information.* CCC may require a DMA to submit updated information, a new application, or a request for recertification whenever CCC becomes aware of any changes or has any reason to be uncertain that the DMA is operating in a manner that is consistent with the information already submitted, or consistent with this part.

(d) *Annual recertification.* Within 4 months after the end of the DMA's fiscal year, a DMA must submit the following information to CCC:

(1) A current financial statement prepared according to generally accepted accounting principles;

(2) A report of audit or review of the financial statement conducted by an independent Certified Public Accountant. The accountant's report of audit or review shall include the accountant's certifications, assurances, opinions, comments, and notes with respect to such financial statements.

(3) Additional financial security as determined by CCC, if the financial security on file with CCC does not meet current requirements or has expired.

(4) A report of changes as required under paragraph (a) of this section.

(e) *Activity report.* DMA's shall provide CCC reports of MAL and LDP volume and benefit earnings made by the DMA for individual producers, and gains received on behalf of each peanut producer, in a format as directed by CCC.

§ 1421.408 Suspension and termination.

(a) *Suspension.* If CCC determines that a DMA is not in compliance with the DMA agreement CCC may suspend the DMA from making peanut MAL's and LDP's until the DMA corrects the violation, or longer.

(b) *Termination.* The DMA agreement may be terminated by the DMA upon 30-calendar day's written notice to CCC. CCC may cancel the agreement at any time. Upon termination DMA shall immediately cease processing MAL or LDP requests and documents except as needed to preserve CCC's position with respect to existing loans or LDP's.

§ 1421.409 Prohibited activity.

(a) DMA's approved to handle loans under this subpart may not:

(1) Discriminate against or deny any producer from receiving MAL's or LDP's because of race, color, national origin, gender, religion, age, disability, political beliefs, sexual orientation, and marital or family status for which they would otherwise be eligible under the statutes regulating the MAL and LDP program.

(2) Pool peanuts for the purpose of obtaining peanut MAL's or LDP's from CCC.

(3) Pool the proceeds obtained from peanut MAL's or LDP's made by CCC.

(4) Process farm-stored certified or measured MAL's or LDP's unless authorized by CCC.

(5) Take title to any peanuts.

(6) Operate the DMA under the same entity and tax identification number of a CCC-approved CMA.

(7) Refuse services to producers because the DMA was not granted a power of attorney for purposes of executing MAL documents to obtain MAL's for the producer, repaying the MAL for the producer, obtaining LDP's for the producer, or marketing the producer's peanuts.

(8) Adopt any scheme or device to circumvent the purpose of the peanuts MAL and LDP program regulations, the regulation governing DMA's, or the DMA's agreement with CCC.

(9) Process MAL's or LDP's for producers involved in a bankruptcy proceeding unless authorized by CCC.

(10) Process MAL's or LDP's on ineligible peanuts.

(b) If the prohibitions of this section are violated FSA or CCC may take one or more of the actions authorized in this part or otherwise authorized.

§ 1421.410 Monitoring payment limitations.

DMA's shall monitor potential gains for producers and not disburse proceeds or permit loan repayments in lieu of forfeitures of the peanuts that would produce a gain over the per person per year limit allowed to the producer by this part and part 1400 of this chapter or which would otherwise be prohibited.

§ 1421.411 Recordkeeping requirements.

A DMA shall maintain producer MAL and LDP paper documents and electronic records for an indefinite period unless otherwise notified by CCC.

§ 1421.412 Forms.

For purposes of conducting business related to this part, a DMA shall use either current CCC forms or other forms approved by CCC. A DMA may perform functions under this part only when approval has been obtained by CCC.

§ 1421.413 Powers of attorney.

DMA's may hold a power of attorney from a producer allowing the DMA to

sign MAL and LDP documents for the producer, but DMA's may obtain and hold such powers only in accordance with the requirements of CCC governing such powers.

§ 1421.414 Liens and waivers.

DMA's performing loan-related functions pursuant to the authority in this subpart shall determine, to the same extent as required for loans handled by FSA county offices, whether a lien on the peanuts exists by performing or obtaining a lien search for all peanuts to be pledged for each MAL, except that the cost associated with such lien search and any necessary lien waivers shall be borne by the DMA. If a lien exists, the DMA shall obtain, on an approved CCC form, a signed waiver from each lienholder with an interest in any such lien.

§ 1421.415 Producer request to a DMA for an MAL or LDP.

Peanut producers or their authorized agent may request that an MAL or LDP be processed by a DMA only if the DMA is approved under this subpart to process such a request and only if the producer supplies to the DMA:

(a) *Beneficial interest information.* Beneficial interest must be maintained by the producer according to § 1421.6 for the peanuts to be eligible for MAL or LDP; accordingly, the producer must supply to the DMA such information as it needed to make that determination.

(b) *Warehouse receipts and lien information.* Producers must supply for all peanuts either individual paper warehouse receipts in the producer's name or an electronic warehouse receipt (EWR) number and provider's name. Producers must supply relevant lien information regarding the peanuts; however, the producer's obligation in this regard does not relieve the DMA from making the appropriate lien search.

§ 1421.416 Processing marketing assistance loans.

DMA's shall take the following actions in the following order when an application for an MAL is filed:

(a) Make all the determinations that are a precondition for a loan, including lien determinations and if requested by the producer, enter into a power of attorney agreement with the producer.

(b) If there is an EWR for the peanuts, instruct the current holder to notify the electronic warehouse receipt provider to amend the electronic warehouse receipt to show the DMA as holder. If a paper receipt is involved, the DMA must obtain the receipt (and later, at the appropriate time include the receipt in the documents delivered to the CCC).

(c) Complete all MAL forms.

(d) After the producer or the person holding the power of attorney for the producer signs MAL document, provide the signatory with copies of the documents.

(e) Where there is an EWR for the peanuts notify the EWR provider to make CCC the holder of the EWR and secure an affirmation verifying that CCC has been made the holder of the EWR.

§ 1421.417 Processing loan deficiency payments.

(a) DMA's shall take the following actions in the following order when an application for an LDP is filed:

(1) In addition to other determinations as must be made, the DMA shall determined whether the producer has sufficient remaining eligibility under the applicable payment limit to allow the receipt of the LDP. If there is not sufficient eligibility, the DMA must refuse to process the request;

(2) If EWR's are applicable for the peanuts for which the LDP is sought, the DMA must instruct the current holder to notify the EWR provider to amend the EWR to show that the peanuts were used to obtain an LDP;

(3) The DMA must insure that the producer or the person holding the power of attorney for the producer signs the LDP documents; and

(4) If the peanuts and the producer are eligible for the loan and all other conditions have been met, the DMA may disburse funds to the producer subject to the time limits set out elsewhere in this part.

(b) The LDP rate applicable to the LDP request will be the rate in effect on the date the DMA receives the request except as may otherwise be provided for in this part.

§ 1421.418 Disbursing MAL and LDP proceeds.

(a) A DMA may request that CCC establish a drawdown account from which to disburse MAL and LDP amounts to producers, and designate the financial institution they wish to use.

(b) CCC will determine whether a drawdown account is justified and the amount of the account.

(c) If there is no drawdown account, MAL and LDP proceeds shall be distributed to the producer within 3 work days from the date the DMA receives MAL or LDP proceeds from CCC, after deduction of authorized charges or fees for services. If there is a drawdown account, the MAL and LDP proceeds shall be distributed to the producer within 3 days of the completion of the application.

(d) The DMA shall assess charges and fees at the same rate for each producer that it serves.

(e) If a drawdown account is used, CCC shall replenish the amount as necessary as it is drawn down.

(f) The DMA must notify CCC of the actual date on which the MAL is disbursed.

§ 1421.419 Date storage credit begins on DMA-handled loans.

Storage credit in favor of a producer with respect to peanuts on a DMA-handled loan will begin on the date on which DMA disburses the MAL to the producer and not before.

§ 1421.420 Submitting MAL and LDP documentation to FSA.

(a) Until such time as an alternative FSA loan or LDP making system is made available to DMA's, within 3 business days of any DMA prepared disbursement, the DMA shall group separately and submit to FSA:

(1) MAL's with the same disbursement date, peanut type, warehouse code, and State where peanuts were inspected; and

(2) LDP's with the same LDP rate, approval date, and peanut type.

(b) Each of the groups identified in paragraph (a) of this section shall be submitted to FSA with the following documents:

(1) Individual paper warehouse receipts or EWR numbers, and the EWR provider's name representing the bundled MAL's or LDP's.

(2) A form to itemize receipts, and other data, as required, or a pre-processed electronic file containing data required by FSA.

(c) FSA may process each DMA prepared MAL or LDP group for the volume of peanuts on multiple receipts as one MAL or LDP, waive the service fee to the DMA, and either hold MAL paper warehouse receipts, or verify that CCC is holder of the EWR's as of the date of disbursement.

(d) In the case of an MAL, if CCC was not the holder of the EWR on or before the date the DMA prepared MAL was disbursed, the applicable receipts shall be rejected, and funds shall not be distributed to the DMA drawdown account until CCC becomes the holder of the EWR.

(e) If MAL and LDP documentation is acceptable, FSA will disburse MAL or LDP funds to the DMA, with appropriate supporting documentation.

§ 1421.421 MAL or LDP servicing.

(a) The DMA shall be responsible for servicing MAL's and are required to take the following actions:

(1) Send the producer a maturity notice letter before MAL maturity.

(2) Maintain the MAL or LDP documents according to FSA requirements.

(3) Transmit the necessary funds to repay the MAL to FSA.

(b) FSA shall process the CCC release of paper receipts or EWR's where such a release is appropriate.

§ 1421.422 Inspections and reviews.

The books, documents, papers, and records of the DMA and parent company shall be maintained for six years after the applicable crop year and shall be made available to CCC for inspection and examination at all reasonable times. At any time after an application is received, CCC shall have the right to examine all books, documents, papers, and determine whether the DMA is operating or has operated in accordance with the regulations in this part, any articles of incorporation, articles of association, partnership documents, agreements with producers, the representations made by the DMA in its application for approval, and, where applicable, its agreements with CCC. If the DMA is determined to be not complying with this part or any of its agreements, CCC will take appropriate action as provided in elsewhere in this subpart or other action CCC determines appropriate.

§ 1421.423 Appeals.

Parts 11 and 780 of this title apply to this subpart.

Signed in Washington, DC, on May 25, 2005.

James R. Little,

Executive Vice President, Commodity Credit Corporation.

[FR Doc. 05–11505 Filed 6–9–05; 8:45 am]

BILLING CODE 3410–05–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 94

[Docket No. 04–091–2]

Addition of Malaysia To List of Regions in Which Highly Pathogenic Avian Influenza Subtype H5N1 Is Considered To Exist

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Affirmation of interim rule as final rule.

SUMMARY: We are adopting as a final rule, without change, an interim rule that amended the regulations concerning the importation of animals and animal products by adding Malaysia to the list of regions in which highly pathogenic avian influenza (HPAI) subtype H5N1 is considered to exist. We took that action to prevent the introduction of HPAI subtype H5N1 in the United States.

DATES: The interim rule became effective on August 7, 2004.

FOR FURTHER INFORMATION CONTACT: Dr. Julie Garnier, Staff Veterinarian, Technical Trade Issues Team, National Center for Import and Export, VS, APHIS, 4700 River Road Unit 39, Riverdale, MD 20737–1231; (301) 734–5677.

SUPPLEMENTARY INFORMATION:

Background

Highly pathogenic avian influenza (HPAI) is an extremely infectious and fatal disease of poultry and a wide variety of other birds. HPAI can strike poultry quickly without any infection warning signs and, once established, the disease can spread rapidly from flock to flock. In some instances, strains of HPAI viruses can be infectious to people. Human infections with AI viruses under natural conditions have been documented in recent years. Particularly alarming is the HPAI strain of most of these outbreaks, H5N1, which has crossed the species barrier and caused severe disease, with high mortality, in humans. Recent outbreaks of HPAI in Southeast Asia have caused significant concern among health authorities worldwide because of the potential for the human and avian flu viruses to swap genes, creating a new virus to which humans would have little or no immunity.

The Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture (USDA or the Department) regulates the importation of animals and animal products into the United States to guard against the introduction of animal diseases. The regulations in 9 CFR parts 93, 94, and 95 (referred to below as the regulations) govern the importation of certain animals, birds, poultry, meat, other animal products and byproducts, hay, and straw into the United States in order to prevent the introduction of various animal diseases, including HPAI subtype H5N1.

In an interim rule effective August 7, 2004, and published in the **Federal Register** on February 1, 2005 (70 FR 5043–5044, Docket No. 04–091–1), we amended the regulations in part 94 by adding Malaysia to the list of regions in § 94.6(d) where HPAI subtype H5N1 exists.

Comments on the interim rule were required to be received on or before April 4, 2005. We received one comment by that date, from a private citizen. The commenter supported the interim rule.

Therefore, for the reasons given in the interim rule and in this document, we are adopting the interim rule as a final rule without change.

This action also affirms the information contained in the interim rule concerning Executive Order 12866 and the Regulatory Flexibility Act, Executive Order 12988, and the Paperwork Reduction Act.

Further, for this action, the Office of Management and Budget has waived its review under Executive Order 12866.

List of Subjects in 9 CFR Part 94

Animal diseases, Imports, Livestock, Meat and meat products, Milk, Poultry and poultry products, Reporting and recordkeeping requirements.

PART 94—RINDERPEST, FOOT-AND-MOUTH DISEASE, FOWL PEST (FOWL PLAGUE), EXOTIC NEWCASTLE DISEASE, AFRICAN SWINE FEVER, CLASSICAL SWINE FEVER, AND BOVINE SPONGIFORM ENCEPHALOPATHY: PROHIBITED AND RESTRICTED IMPORTATIONS

■ Accordingly, we are adopting as a final rule, without change, the interim rule that amended 9 CFR part 94 and that was published at 70 FR 5043–5044 on February 1, 2005.

Done in Washington, DC, this 6th day of June 2005.

Elizabeth E. Gaston,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 05–11504 Filed 6–9–05; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Parts 319 and 381

[Docket No. 92–024F]

Rin 0583–AC82

Food Standards: Requirements for Substitute Standardized Meat and Poultry Products Named by Use of an Expressed Nutrient Content Claim and a Standardized Term

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is amending the Federal meat and poultry products inspection regulations to establish a general definition and standard of identity for standardized meat and poultry products that have been modified to qualify for use of an expressed nutrient content claim in their product names. These products will be identified by an expressed nutrient content claim, such as ''fat free,'' ''low fat,'' and ''light,'' in conjunction with an appropriate standardized term, *e.g.*, ''low fat bologna.'' FSIS is taking this action to: Assist consumers in maintaining healthy dietary practices by providing for modified versions of standardized meat and poultry products that have reductions of certain constituents that are of health concern to some consumers, such as fat, cholesterol, and sodium; increase regulatory flexibility and support product innovation, and provide consumers with an informative nutrition labeling system.

DATES: This final rule will be effective January 1, 2008, the uniform compliance date for all meat and poultry products subject to labeling regulations issued by FSIS between January 1, 2005 and December 31, 2006. However, establishments may begin to produce meat and poultry products in compliance with this final rule anytime before the effective date.

FOR FURTHER INFORMATION CONTACT: Dr. Robert Post, Director, Labeling and Consumer Protection Staff, Office of Policy, Program, and Employee Development, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250–3700; (202) 205–0279.

SUPPLEMENTARY INFORMATION:

Background

On December 29, 1995, FSIS published a proposed rule in the **Federal Register** to amend the Federal meat and poultry products inspection regulations to establish a general definition and standard of identity (the ''general standard'') for standardized meat and poultry products that have been modified to qualify for use of an expressed nutrient content claim in their product names (60 FR 67474). Under the proposed general standard, meat and poultry products with a regulatory standard of identity or composition in 9 CFR Parts 319 and 381, subpart P, would be permitted to be formulated and processed with ingredients otherwise not provided for, or in amounts greater than, that allowed by the standard in order to qualify for certain expressed nutrient content claims permitted in 9 CFR 317 subpart B and 381, subpart Y, such as ''fat free,'' ''low fat,'' and ''light.'' Instead of being identified as ''substitute'' standardized meat and poultry products, as required by the current regulations (9 CFR 317.313(d) and 381.413(d)), standardized meat and poultry products formulated or processed in accordance with the proposed general standard could be identified by an expressed nutrient content claim in conjunction with the standardized term.

To allow modified versions of standardized meat and poultry products that have been formulated to reduce their fat content to be marketed without having to be labeled as ''substitutes,'' FSIS issued Policy Memo 123, ''Modified Breakfast Sausage, Cooked Sausage, and Fermented Sausage Products Identified by a Nutrient Content Claim and a Standardized or Traditional Name,'' and Policy Memo 121B ''Labeling of Low Fat Ground Beef and Low Fat Hamburger Containing Added Ingredients,'' in January of 1995. These policy memoranda stated, among other things, that these products are permitted to be identified by a nutrient content claim that reflects the reduction in fat content in the product in conjunction with the appropriate standardized product name, *e.g.*, ''Fat Free Bologna,'' ''Low Fat Pepperoni,'' or ''Low Fat Hamburger, Water, and Carrageenan Product.'' Both Policy Memo 121B and Policy Memo 123 were issued as interim measures until such time that rulemaking could be completed. Both of these policy memoranda will be rescinded by this final rule.

In this final rule, FSIS is establishing a general definition and standard of identity for modified versions of meat and poultry products that substitute for meat and poultry products defined by a regulatory standard of identity or composition in 9 CFR Part 319 and 381, subpart P, *i.e.*, ''substitute standardized products.'' This rule is needed to facilitate the development and availability of substitute standardized meat and poultry products that have reductions in constituents that are of health concern to some people, *e.g.*, fat, cholesterol, and sodium. The rule allows FSIS to rely more on labeling requirements and less on restrictive recipe-type standards to carry out its mandate to ensure that the labels of meat and poultry products are truthful and not misleading to consumers.

Comments and Agency Response

FSIS received 56 comments in response to the proposed rule from members of the meat and poultry processing industry, industry trade associations, members of the flavoring and ingredients industry, members of the soybean industry, academia, health professionals, governmental entities, consumer advocacy groups, and individual consultants. In general, the comments submitted in response to the proposed rule were favorable. Most commenters agreed that FSIS should establish a regulatory general standard for substitute standardized products that are lower in fat, cholesterol, or sodium.

One commenter opposed the rule because the commenter believed it did not go far enough in providing flexibility to industry. This commenter stated that, rather than converting FSIS Policy Memo 123 into regulation, FSIS should create a new standard for substitute standardized meat and poultry products to allow the use of non-traditional ingredients in all products, not just versions of products that are identified by a nutrient content claim and a standardized product name.

Response: FSIS recognizes the need to explore this and other issues concerning reform of the meat and poultry product standards. However, expanding the use of non-traditional ingredients for all standardized products is an issue that is outside the scope of this rulemaking. The Agency is, however, exploring this and other related issues in a separate rulemaking to modernize meat and poultry product standards. This rulemaking is discussed in greater detail later in this document.

Policy Memo 123 and Policy Memo 121B

Comment: A few commenters felt that FSIS Policy Memo 121B and Policy Memo 123 should remain in effect once this final rule becomes effective so that products produced under these policies can continue to be manufactured. Other commenters stated that the general standard defined in the proposed rule should apply to food products whose standards are documented in the FSIS Food Standards and Labeling Policy Book (the Policy Book), as well as those products whose standards of identity and composition are codified in Parts 319 and 381, subpart P. The commenters noted that the wording in proposed 9 CFR 319.10(a) and 381.172(a) does not specifically include the standards described in the Policy Book, while FSIS Policy Memo 123 does. They were concerned that once the rule is in place, and Policy Memo 123 is rescinded, certain products, such as ''Low Fat Pepperoni,'' would no longer be permitted because pepperoni

does not have a standard of identity codified in the regulations.

Response: The policy embodied in the proposed general standard will also apply to the informal standards for products, such as pepperoni, that are described in the Policy Book. Thus, Policy Memo 121B and Policy Memo 123 will not remain in effect once the proposed rule becomes final. FSIS issued both Policy Memo 121B and Policy 123 as interim measures to accommodate certain lower fat substitute meat and poultry products until such time that rulemaking was completed. This final rule incorporates, expands, and codifies the intent of these policy memoranda. Thus, rescinding Policy Memo 121B and Policy Memo 123 will not preclude the production of products that have been made under those policies. The Agency intends to clarify this point in a policy bulletin, which is a more appropriate document for addressing the informal standards described in the Policy Book.

Nutrient Content Claims That Emphasize the Presence of an Ingredient

Comment: Some commenters disagreed with the Agency's proposal to permit only expressed nutrient content claims that relate to reductions in constituents such as fat, cholesterol, or sodium, in conjunction with the standardized name of the substitute product. These commenters felt that nutrient content claims, such as ''high in'' and ''good source of,'' that emphasize the presence of an ingredient, should also be permitted to be used as part of the substitute standardized product's name, provided that the product qualifies for these claims under 9 CFR part 317 subpart B or 9 CFR 381 subpart Y.

Response: Under the current regulations, meat and poultry products that satisfy the criteria for use of nutrient content claims defined in 9 CFR part 317 subpart B and 9 CFR 381 subpart Y are permitted to make claims, such as ''high in'' or ''good source of,'' that emphasize the presence of a nutrient. The ability to make these kinds of nutrient content claims is not affected by this rulemaking.

In the preamble to the proposed rule, FSIS noted that the meat and poultry product standards did not appear to preclude the making and marketing of standardized products that qualify for the use of claims such as ''high in'' and ''good source of.'' Therefore, in the proposed regulation, the Agency did not expressly provide for these types of nutrient content claims in the general standard. However, in the proposal, FSIS did solicit comments on whether current regulatory standards prevent the distribution of products with nutrient content claims other than those that reflect a reduction in the level of a nutrient.

None of the comments received suggested that the existing meat and poultry product standards preclude the making and marketing of standardized products that qualify for the use of claims such as ''high in'' or ''good source of.'' Furthermore, because of the FSIS policy that precludes direct nutrient fortification of meat and poultry products, standardized meat and poultry products are not permitted to be modified to qualify to use a nutrient content claim by adding nutrients to the product. Therefore, FSIS has decided not to modify the scope of coverage in this final rule to permit nutrient content claims other than those that reflect a reduction of constituents that are of health concern to some people, *e.g.*, fat, cholesterol, and sodium, to be used as part of the product name. Products that qualify for ''high in'' and ''good source of'' nutrient content claims may continue to highlight these claims as provided in 9 CFR 317.354 and 9 CFR 381.454.

Nutrient Fortification

Comment: Four commenters suggested that FSIS reexamine its policy precluding direct nutrient fortification of meat and poultry products. Two of these commenters suggested that FSIS allow selective nutrient fortification in meat and poultry products to permit standardized products to be modified so that they qualify to use nutrient content claims, such as ''high in Vitamin A,'' as part of the product name. One of these commenters requested that FSIS modify the language in proposed 9 CFR 319.10(a) to delete the following italicized words ''* * * because of a *compositional* deviation that *results from reduction of a constituent that* is described by an expressed nutrient content claim * * *''

Another commenter suggested that FSIS permit selective protein fortification in substitute standardize products so that they may use claims such as ''High in Protein'' and ''Good Source of Protein'' as part of the product name. This commenter recommended that FSIS continue to require substitute standardized products to meet the same basic minimum meat and poultry content requirements contained in the existing meat and poultry product standards, but that the overall protein level in these products should be allowed to be fortified using ingredients such as soy protein. Another commenter that expressed support for permitting direct nutrient fortification of meat and poultry products felt that, because the over-consumption of protein in the American diet, that protein fortification should not be permitted.

Two other commenters requested that FSIS allow fortification to replace vitamins and minerals that may be lost due to formulation adjustments to produce nutrient-modified foods. These commenters also requested that FSIS exempt substitute standardized products subject to the general standard from the minimum meat and poultry content requirements imposed by the existing meat and poultry product standards. Both commenters suggested that for these substitute products, FSIS should focus on nutritional equivalency to the traditional standardized product rather than meat content equivalency, and permit reductions in the meat and poultry content for purposes of reducing the product's fat content. The commenters stated that if FSIS were to permit such reductions in the meat and poultry content, fortification might be necessary to replace lost nutrients.

One commenter suggested that, while existing FDA regulations state that the FDA does not consider it appropriate to fortify meat and poultry products (21 CFR 104.20(a)), the FDA regulations appear to make an exception for fortification of foods that replace traditional foods when fortification is necessary to avoid nutritional inferiority.

Response: The comments requesting that FSIS reexamine its policy on nutrient fortification raise some interesting points, particularly with respect to the issues concerning nutritional equivalency versus meat content equivalency. However, the decision to allow fortification of meat and poultry products involves several complex issues, many of which are outside the scope of this rulemaking.

FSIS'' fortification policy is derived from FDA's policy statement on nutrient fortification codified at 21 CFR part 104, subpart B, which states, in part, that the FDA ''* * * does not consider it appropriate to fortify fresh produce; meat, poultry, or fish products * * * (21 CFR 104.20(a)). The fundamental objective of FDA's fortification policy is ''* * * to establish a uniform set of principles that will serve as a model for the rational addition of nutrients to food'(21 CFR 104.20(a)). As stated in its policy, FDA determined that, ''* * * random fortification of foods could result in over-or under-fortification in consumer diets and create nutrient imbalances in the food supply'' (21 CFR 104.20(a)).

FSIS has a long history of prohibiting direct fortification of meat and poultry products, which is supported by the codified FDA fortification policy. Thus, when determining whether to revise its nutrient fortification policy for meat and poultry products, FSIS must consider the issues in relationship to the codified FDA policy statement on fortification. Furthermore, in order to maintain consistent policies regarding nutrient fortification between the two agencies, any effort by FSIS to revise its prohibition on direct nutrient fortification of meat and poultry products should include FDA participation and involve the scientific community (*e.g.*, the National Academy of Sciences, Institute of Medicine). FSIS, FDA, and the scientific community need to first consider the guiding scientific principles that form the basis for establishing a public health need for fortifying meat and poultry with nutrients. Only after these principles are applied could there be consideration of revising the current fortification policy.[1] Obviously, this type of effort is outside the intended purpose and scope of this rulemaking. It would be more appropriate to consider this matter in a separate rulemaking where the Agency can receive the benefit of an open and thorough review of all issues related to the fortification of meat and poultry products.

Furthermore, FSIS believes that the formulation adjustments needed to produce substitute standardized products with reductions in constituents such as fat, cholesterol, and sodium, will not result in a product that is nutritionally inferior to the product for which it is a substitute. Important nutrients, such as iron, zinc, B vitamins, and protein, are associated with the lean muscle portion of meat and poultry tissue, not the fat. Because the minimum meat and poultry requirement for substitute standardized products is not changed by this rule, reductions in the fat content should not affect the levels of nutrients associated with the lean muscle portion of these products. Therefore, nutrient fortification is not necessary to prevent the products subject to the general standard defined by this rule from being nutritionally inferior to the standardized products for which they are a substitute.

[1] See report: Institute of Medicine, National Academy of Science, 2003. Dietary Reference Intakes, Guiding Principles for Nutrition Labeling and Fortification. The National Academies Press, Washington, DC.

Differences in Performance Characteristics

Comment: The proposed regulation stated that a substitute standardized product with performance characteristics, *e.g.*, cooking quality, freezing quality, spreadability of product, and shelf-life, that materially limit the use of the product must include a disclaimer on the product's label adjacent to the product name informing the consumer of such differences.

Most commenters agreed that limitations in a product's performance characteristics should be disclosed on the product label, and be conspicuous and readable. A number of commenters stated that the disclaimer should be adjacent to the most prominent claim on the label. One commenter, although in agreement with the disclaimer requirement, felt that disclosure on the label, not necessarily adjacent to the product name as provided in the proposed rule, was sufficient to inform the consumer of performance differences. This same commenter recommended that FSIS harmonize the requirement for labeling of performance differences with a similar FDA rule, which requires a disclaimer adjacent to the most prominent claim on the label (21 CFR, 101.13(d)). Another commenter stated that the disclaimer should be adjacent to the most prominent claim and should most likely appear on the principal display panel.

Response: In the preamble to the proposed rule, FSIS stated that ''if there is a difference in performance characteristics that materially limits the use of the product, the product may still be considered a substitute if the label includes a disclaimer adjacent to the most prominent claim in accordance with 9 CFR 317.313(d)(1) and (2) and 9 CFR 381.413(d)(1) and (2), informing the consumer of such difference'' (60 FR 67480). However, in the text of the proposed rule, FSIS stated that the label must include, ''adjacent to the product name,'' a statement in accordance with 9 CFR 317.313(d)(1) and (2) and 9 CFR 381.413(d)(1) and (2) informing the consumer of differences in performance characteristics (60 FR 67486, 67487). Thus, the preamble and the text of the proposed rule differed in that the preamble did not mention that the disclaimer must be ''adjacent to the product name.'' The regulations referenced by both the preamble and the text of the proposed rule, 9 CFR 317.313(d)(1) and 9 CFR 381.413(d)(1), require that differences in performance characteristics that materially limit the performance of a substitute product be disclosed adjacent to the most prominent claim on the product label.

FSIS is resolving the discrepancy regarding placement of the disclaimer. FSIS agrees with the comment that disclosure on the label, not necessarily adjacent to the product name, is sufficient to inform the consumer of performance differences. Therefore, in this final rule, FSIS is not requiring that the disclaimer be placed adjacent to the product name. As in FDA regulations 21 CFR 130.10 and 101.13(d), a disclaimer for differences in performance characteristics shall be placed adjacent to the most prominent claim on the label. To reflect this decision, FSIS is removing the phrase ''adjacent to the product name'' from proposed §§ 319.10(b)and 381.172(b).

Comment: Two commenters disagreed with the need for the proposed disclaimer requirement and suggested that disclosure of any limitations in the performance characteristics of a substitute standardized product be voluntary. One of these commenters stated that disclaimers on a product's labeling informing consumers of performance characteristics that materially limit the use of the product need not be required by regulations because a substitute standardized product produced under the general standard will succeed or fail in the market place based on consumer expectations associated with the product's performance. This commenter stated that businesses would voluntarily place disclaimers on a product's label in the absence of a regulation requiring that they do so because it would be good business to inform consumers that a product they are purchasing can not be used in a traditional application.

The other commenter agreed that, in practice, poorly formulated products would fail in the marketplace long before any regulatory system could determine that they did not meet the specific performance characteristics they would be expected to have. However, this commenter acknowledged that requiring a disclaimer informing consumers of limitations in a product's performance characteristics, when they exist, will require manufacturers of substitute standardized products to monitor performance characteristics during product development and may help ensure that new low- and reduced-fat standardized products are formulated well from the beginning. The commenter went on to state that consumers are also more likely to accept this category of substitute products if they are well formulated from the beginning.

Response: FSIS disagrees with the commenters' suggestion that disclosure of performance characteristics that materially limit the use of a substitute standardized product compared to the use of the traditional standardized product should be voluntary. The FMIA and the PPIA require that the labeling of a meat or poultry product must be truthful and not misleading, and that such labeling accurately disclose to consumers what they are buying when they purchase any meat or poultry product. Information disclosing differences in performance characteristics that affect the use of a substitute standardized product (*e.g.*, cooking quality, freezing quality, spreadability of product, and shelf life) is a material fact that must be disclosed on the labeling of these products. Without such labeling, consumers would be misled about significant characteristics and uses the product has compared to the standardized product for which it substitutes. Accordingly, this information must be communicated to consumers on the product's label, or the label will be misleading and the product will be misbranded under the FMIA or PPIA.

Moreover, FSIS agrees with the commenter who suggested that processors are more likely to monitor the performance characteristics of substitute standardized products during product development when limitations in the product's performance characteristics are required to be disclosed on the product's labeling. FSIS also agrees that if substitute standardized products are well formulated from the beginning, it will promote consumer acceptance of this category of meat and poultry products.

Comment: One commenter pointed out that it may be possible for performance characteristics to be introduced into a substitute standardized product that improve upon the performance characteristics of the traditional standardized product. The commenter suggested that the Agency consider substituting the term ''not inferior'' for ''similar'' in proposed 9 CFR 319.10(b).

Response: FSIS did not intend to prohibit improvements in the performance characteristics of substitute products when it proposed that substitute standardized products subject to the general standard perform similarly to the traditional standardized products for which they substitute. However, FSIS disagrees that it should require that substitute standardized products have performance characteristics that are ''not inferior to'' rather than ''similar to'' the traditional standardized products as suggested by the commenter. As proposed, §§ 319.10(b) and 381.172(b) permit products subject to the general standard to have limitations in performance characteristics provided that such limitations are properly disclosed on the product's labeling. The Agency believes that requiring disclosure of any performance limitations on the labeling of products subject to the general standard provides sufficient incentive for manufacturers of these products to market products that are not inferior to the traditional standardized products. Furthermore, proposed 9 CFR 319.10(b) and 9 CFR 381.172(b) require a disclaimer for performance characteristics that ''materially limit'' the use of a substitute standardized product, not for characteristics that improve the performance of the product. Thus, the disclaimer requirement contained in proposed 9 CFR 319.10(b) and 9 CFR 381.172(b) will not discourage manufacturers from making improvements to the performance characteristics of substitute products when it is possible to do so.

Enforcement

Comment: Two commenters questioned FSIS's ability to enforce and ensure uniform compliance with the performance characteristics requirements proposed in 9 CFR 319.10(b) and 381.172(b). One commenter asked how FSIS intends to determine differences in performance characteristics. The commenter went on to state that the proposed performance characteristics requirements seem to be ''command and control'' regulations that are not related to product safety. The other commenter stated that, in practice, poorly formulated products would fail in the marketplace long before any regulatory system could determine that they did not meet the specific performance characteristics discussed in the proposal.

Response: FSIS expects that substitute standardized products that are produced under the general standard will conform to the performance characteristics requirements set forth in proposed 9 CFR 319.10(b) and 381.172(b). To ensure that there is compliance, FSIS will examine the performance characteristics and product quality of substitute products as it would other types of products, through scientific review and experimental investigations. In addition, FSIS will use traditional methods available to the Agency, such as sample analysis, inspections, surveys, and follow-up investigations of consumer and trade complaints to identify products that do not comply with the new regulations in order to enforce this regulation as the need arises.

Furthermore, FSIS disagrees with the comment that the proposed performance characteristics requirements are ''command and control'' regulations. Under §§ 319.10(b) and 381.172(b), FSIS is not establishing specific criteria for determining similarities in performance characteristics. FSIS believes that judgments about similarity are best left to product developers, who have the incentive to market a product that resembles the traditional standardized product as closely as possible and to disclose product performance limitations to ensure that there is consumer satisfaction with the substitute standardized product.

Safe and Suitable Ingredients

Comment: There was general agreement among the commenters that the ingredients used in a substitute standardized product produced under the general standard should be those ingredients provided by the traditional standard, with the exception of ''safe and suitable ingredients,'' as defined in (former) 9 CFR 318.7 and 381.147, at the minimum level necessary to improve texture and prevent syneresis. However, several commenters requested clarification and expansion of the ingredients permitted under this provision.

Three commenters stated that allowances for ingredients should be broadened to include any safe and suitable ingredients to replace functional characteristics. These commenters all noted that the FSIS proposal limits ingredient usage to achieve textural improvement and to prevent syneresis. They felt that FSIS should build additional flexibility into the final rule to allow for a wider use of safe and suitable ingredients to replace functional characteristics that may be lost when a formulation is adjusted to meet a claim requirement. These commenters mentioned that the comparable FDA regulation allows the use of safe and suitable ingredients ''* * * to add flavor, extend shelf life, improve appearance, or add sweetness'' (21 CFR 130.10(d)). One commenter suggested that any ingredient that is generally recognized as safe (GRAS) or that is an approved additive should be permitted to be used as desired by the manufacturer. Another commenter stated that limiting the use of safe and suitable ingredients to the minimum level necessary to improve texture and to prevent syneresis severely limits the ability to produce a consumer-acceptable meat or poultry product. One

commenter specifically requested that FSIS clarify the acceptability of flavorings, especially meat flavorings, as safe and suitable ingredients in substitute standardized products.

Response: For purposes of clarification, since it published the general standard proposal, FSIS issued the final rule ''Food Ingredients and Sources of Radiation Listed or Approved for Use in Meat and Poultry Products'' (64 FR 72168, December 23, 1999). The rule is intended to improve the efficiency of the procedures used by FSIS and FDA to review and approve the use of food ingredients and sources of radiation in the production of meat and poultry products. Under the new regulations, rather than listing substances approved for use in the production of meat and poultry products in the chart of substances contained in former 9 CFR 318.7(c)(4) and former 9 CFR 381.147(f)(4), FDA now lists food ingredients and sources of radiation that are safe for specific use in the production of meat and poultry products in its regulations in title 21 of the CFR. In the final rule, FSIS also created a list of food ingredients approved for use in the production of meat and poultry products by combining the listing contained in former section 318.7(c)(4) with the listing contained in former section 381.147(f)(4) and moving the combined listing to section 424.21(c). The final rule became effective on January 24, 2000.

FSIS did not include ingredients that would affect flavor, shelf life, or sweetness because these kinds of ingredients do not affect the ability of a manufacturer to modify a meat or poultry product to reduce fat, cholesterol, or sodium, which was the focus of this rulemaking. Thus, §§ 319.10 and 381.172 provide only for increased amounts of safe and suitable ingredients that are needed to achieve the effect of replacing fat, *i.e.*, binders, texturizers, and emulsifiers.

As for the acceptability of flavorings in substitute standardized products, manufacturers will not be limited by §§ 319.10 or 381.172 in their ability to use ingredients that impart flavor. This final rule does not limit a manufacturer's ability to use safe and suitable meat and poultry flavorings.

''Fat Replacing'' Binders

Comment: In the preamble to the proposed rule, FSIS provided a list of ''fat replacing'' binders to assist meat and poultry processors to understand the types of ingredients that are permitted to be used to achieve the effects of fat in making substitute standardized products under the general standard. However, the list was not intended to be all-inclusive. One commenter supported the use of ingredients not identified in the preamble as part of a fat replacement system and requested that FSIS clarify whether other fat replacers, such as milk protein concentrates, would be permitted in substitute standardized products, given this substance's similarities to the listed substances. The commenter also requested that the preamble to the final rule specifically note that milk protein concentrates and egg whites are acceptable substances in fat replacement systems.

Three commenters agreed that the ingredients listed in the preamble are appropriate for use in a substitute version of a standardized product but felt that the list should be broadened to include other safe and suitable ingredients that have a demonstrated ability to function as a fat replacement system. One of these commenters requested that if the list provided within the context of the preamble is not meant to be all-inclusive, FSIS should state that fact. The commenters also encouraged FSIS to include a list of criteria for evaluating fat replacing binders not on the list to determine whether they qualify as acceptable binders.

Response: The list of ''fat-replacing binders'' presented in the preamble to the proposed rule represents examples of ingredients or additives historically classified as binders by food scientists and ingredient technologists. This list is not intended to be all encompassing, and other safe and suitable ingredients historically recognized as binders are permitted to be used in ''fat replacement'' systems for substitute standardized products produced under the general standard.

In general, a safe and suitable ingredient qualifies for use as a fat replacing binder under this final rule if it is only used for its functional properties and does not impart other characterizing qualities, such as taste and nutritional value, to the standardized product when used in the product formulation. FSIS will evaluate whether safe and suitable ingredients that were not listed in the preamble to the proposal qualify as fat replacing ingredients on a case-by-case basis.

As a point of clarification, milk protein concentrates have historically been used by meat and poultry product manufacturers as binding ingredients in meat and poultry products and therefore, under the general standard, FSIS will permit milk protein concentrates to be used as binders in fat replacement systems for substitute standardized products.

Regarding the use of egg whites as a fat replacing binder, egg whites are considered an egg product and as such function as an individual food product that is consumed for its own taste and nutritional value. Thus, FSIS considers the use of egg whites in the formulation of a meat or poultry product to be sufficiently characterizing so as to result in a product that is not a substitute standardized product, but one that is a non-standardized product, *e.g.*, identified with a true product name, such as ''Low Fat Pork Sausage made with Egg Whites.''

Although FSIS is not providing an all inclusive list of suitable fat replacing binders in this final rule, the Agency did provide an extensive listing of binders in the preamble to the proposed rule to convey the intent of the rule (see 60 FR 67481). Persons interested in determining whether an ingredient is an appropriate fat replacing binder may refer to this original listing.Furthermore, safe and suitable ingredients that meet the general criteria outlined above, *i.e.*, have historically been classified as binders, are only used for their functional properties, and do not impart other characterizing qualities when used in the formulation of substitute products, will also qualify as acceptable fat replacing binders under this final rule.

Textured Vegetable Protein (TVP) as a ''Fat Replacer''

Comment: In the preamble to the proposed rule, FSIS stated that the Agency views TVP as a ''meat or poultry replacer,'' and that the use of TVP as a fat replacing ingredient in a substitute standardized product subject to the general standard would be inappropriate. At the time that the proposal was published, FSIS had determined that the use of TVP in a substitute standardized product would change the nature of the product to such an extent that it would no longer be a substitute product within the parameters of the proposed rule. This view, in part, was based on the belief that TVP was used as a ''meat replacing'' ingredient in foods considered ''meat replacing products,'' such as ''veggie-burgers,'' which are primarily TVP with water, flavorings, and seasonings.

FSIS received numerous comments expressing strong disagreement with FSIS's historic views. Forty-three commenters submitted statements in support of allowing TVP as a fat replacer in substitute standardized meat and poultry products subject to the

general standard so that these products may be identified by a nutrient content claim. Many of these commenters provided supporting studies on the health and nutritional benefits of soy protein, along with data on consumer awareness and acceptance of products containing TVP. Many commenters felt that not permitting TVP as a fat replacing ingredient would greatly limit the ability of the industry to develop substitute standardized meat and poultry products that are lower in fat. These commenters stated that the use of TVP as a fat replacer is important in expanding the flexibility of the meat and poultry industry to create and market an increased variety of healthful substitute meat and poultry products. Some commenters specifically mentioned that prohibiting TVP would limit product development in areas of coarse ground cooked and fermented sausage.

Several commenters stated that TVP should be permitted as a fat replacer so long as its use conforms to the requirements of the general standard. These commenters stated that TVP should be permitted as part of a ''fat replacement system'' in substitute standardized meat and poultry products so long as: (1) Its use does not substantially change the nature of the finished product; (2) it is not used to replace the meat or poultry content required by the traditional standard; and (3) it is used only at the minimum level necessary in a fat replacement system to qualify for use of the nutrient content claim.

A number of commenters stated that TVP should be regulated on the basis of its functional properties rather than on its physical form. Many of these commenters pointed out that, while in the past TVP was used as a ''filler'' or ''substitute'' for meat components in food, advancements in TVP technology have made TVP a highly functional ingredient that could now be used as part of a fat replacement system to improve the textural character and quality of a substitute standardized meat or poultry product. Many commenters noted that TVP, when used in combination with other water binders, provides improved product texture, visual appearance, performance, and storage characteristics. Data supporting this view were presented to the Agency.

Some commenters felt that TVP should be allowed as a fat replacer in all meat items where non-textured vegetable proteins are allowed. One commenter stated that texture is a matter of degree, and that forms of vegetable proteins range from fine powders, to small granules, to small flakes, to larger granules and flakes. This commenter stated that it is arbitrary to require that TVP be excluded as a ''fat replacer'' but not the powdered forms. One commenter questioned the logic of permitting soy flour, soy protein concentrate, and isolated soy protein in products because they replace fat, but prohibiting the use of TVP because it is inappropriately thought to replace meat. The commenter pointed out that the proposed rule does not permit a reduction in the meat or poultry content, and therefore, TVP could not be used as a meat replacer. Another commenter mentioned that other binders, such as carrageenan, can be texturized, and therefore, TVP is being singled out unfairly.

A number of commenters stated that, because the presence of TVP can be disclosed in product labeling, consumers should be allowed to decide for themselves whether to purchase a lower fat standardized product that contains TVP. Some commenters pointed out that the presence of TVP in a meat food product could be communicated to consumers in the same manner as any other ingredient, in the ingredient statement. The commenters asserted that appropriate product labeling required by the general standard would ensure that consumers would not be misled about the presence of TVP in substitute standardized products produced.

Some commenters stated that if TVP is permitted as a fat replacer in substitute standardized products, the substitute product should provide the same amount of animal protein as the traditional standardized product. One commenter stated that this approach would provide manufacturers with optimum flexibility, yet guarantees that the consumer receives a product that is at least as valuable as the unmodified product. Another commenter mentioned that consumers are interested in over-all nutrition, not in specific ingredients.

Some commenters expressed the view that TVP should not be considered as a ''food,'' because it is not consumed by itself as a food. These commenters stated that TVP is a functional food ingredient that can be used as part of a fat replacement system.

Response: FSIS has been persuaded by the comments, information, and other data submitted by commenters to permit the use of TVP as a part of a fat replacing system in substitute standardize products produced under the general standard. Accordingly, in this final rule, proposed §§ 319.10(c) and 381.172(c) have been modified to provide for the use of TVP, alone or in combination with other binders and water, as part of a fat replacement system.

The Agency will permit the use of TVP as a functional food ingredient that is used to replace fat. Like the other fat replacing ingredients permitted to be used under this final rule, the use of TVP as an ingredient in a substitute standardized product will be permitted only at the lowest level necessary to achieve the intended effect of replacing fat. When TVP is used to replace fat, the ingredients statement on the product label must alert the consumer to the fact that TVP is not permitted in the traditional standardized product or is used in excess of amounts permitted in the traditional standardized product. The labeling requirements will ensure that consumers will not be misled when TVP is used to replace fat in substitute standardized meat and poultry products subject to the general standard.

Under this final rule, TVP may not be used to replace the meat or poultry content of a product when a product standard specifies a minimum meat or poultry content requirement. However, if the formulation of a substitute product produced under the general standard contains the same amount of meat or poultry prescribed by the traditional standard, the fat component of the meat or poultry in the substitute product may be removed during processing and replaced with TVP, or any other safe and suitable binder, alone or in combination with water as part of a fat replacement system.

For example, the product standard for ''chili con carne'' provides that the product shall contain not less than 40% meat computed on the weight of the fresh meat (9 CFR 319.300). The product formulation for a substitute version of chili con carne produced under the general standard must contain 40% meat, but the fat content of the meat component may be replaced with TVP during processing.

According to information presented to the Agency, TVP is particularly useful in developing lower fat versions of cooked sausages and other comminuted meat and poultry products. Although the standards for these kinds of products generally do not prescribe a minimum meat or poultry content, most of these standards limit the amount of fat that is permitted in the product. For example, the standard for cooked sausages defined in 9 CFR 319.180 limits the fat content of these products to no more than 30% of the finished product, and the standard for ground beef defined in 9 CFR 319.15 limits the fat content in this product to no more than 30%. Thus, under this final rule, the amount of TVP permitted in such

products will be limited by both the requirement that fat replacing ingredients may be used only at the lowest level necessary to replace fat and by the minimum fat content requirement established by the product standard.

For example, a substitute cooked sausage produced under the general standard is permitted to contain up to 30% TVP, provided that the sole function of the TVP is to replace the fat. For purposes of this rule, FSIS does not consider replacing the fat component of a single ingredient standardized product, such as ground beef, as reducing the product's meat content, provided that the product complies with the manufacturing and labeling requirements prescribed in this final rule.

To eliminate the possibility of confusion, the phrases ''textured vegetable protein shall not replace meat'' and ''textured vegetable protein shall not replace poultry,'' which were used as examples in the regulatory text of proposed 9 CFR 319.10(c)(2) and 381.172(c)(2), will be removed in the final rule. These phrases are unnecessary because the regulation already prohibits reductions in the meat or poultry content required by a regulatory standard regardless of whether TVP is used in the product.

Other Foods as ''Fat Replacers''

Nine commenters indicated that in the final rule, FSIS should permit foods, such as bread, rice, potatoes, fruits, and vegetables to be used in substitute standardized meat and poultry products to reduce their fat content. Some of these commenters stated that these ingredients could serve the same role as the water and binder systems permitted as fat replacers in the proposed rule, but that food ingredients are more beneficial because they may contain some nutritional constituents, such as vitamins and minerals, that many binders do not. One commenter stated that food ingredients, when used at proper levels, help to provide consumers with substitute standardized products that perform similarly to traditional standardized products. Another commenter stated that the nutrition label would enable consumers to make informed purchase decisions based on the entire nutritional profile of the product. This commenter pointed out that many consumers would prefer the nutritional profile of substitute standardized products that use starchy vegetables and complex carbohydrates, such as rice and potatoes, rather than a combination of water and ingredients such as highly refined vegetable gums to lower the percentage of calories from fat. One commenter stated that it makes sense to allow other foods as fat replacers if the goal is to make more healthful products available to consumers. Another commenter suggested that consumers might be more interested in overall nutritional quality, taste, convenience, and performance of the product than in the specific ingredients present in the product.

Response: FSIS concedes that because foods such as bread, rice, potatoes, fruits, and vegetables, have little or no fat, their use as ingredients in standardized meat and poultry product could have the effect of reducing the fat content of such products. However, when foods are used as ingredients in a standardized product, the composition of the product may be altered to such an extent that the resulting product is not a substitute version of the traditional standardized product but a new and different product with a separate identity that reflects the combination of the individual foods. For example, because diced apples and rice are not specified as ingredients in the standardized product ''Pork Sausage,'' when they are added to ''Pork Sausage,'' the result is a new product, which, provided that it does not have a standard of identity or composition prescribed by 9 CFR part 319 or other established common or usual name, is required to bear a descriptive name, such as ''Pork Sausage with Diced Apples and Rice,'' that clearly identifies the product (see 9 CFR 317.2(c)(1) and (e) and 9 CFR 381.117(a)). Because the product ''Pork Sausage with Diced Apples and Rice'' is a new product and not a substitute version of the standardized product ''Pork Sausage,'' it is not the type of product that the general standard established by this final rule is intended to address.

As a point of clarification, this final rule does not prevent non-standardized meat and poultry products that use food ingredients to reduce their fat content from using a traditional nutrient content claim permitted under 9 CFR 317 subpart B and 381 subpart Y, provided they meet the requirements of the claim. For example, the product ''Pork Sausage with Diced Apples and Rice'' is permitted to bear the claim ''low fat'' on its label if it complies with § 317.362, and therefore, may be referred to as ''Low Fat Pork Sausage with Diced Apples and Rice.'' Consumers who prefer the nutritional profile of meat and poultry products that use other foods, rather than binders and water, or other functional food additives, to reduce their fat content will be able to identify these products by their descriptive product name and the traditional nutrient content claim on the product labeling. Furthermore, any benefits in the nutritional profile of products that use foods as ingredients to reduce their fat content will be reflected in the nutrition facts panel, as well, if appropriate, in other nutrient content claims.

Prohibited Ingredients

Comment: One commenter expressed agreement with the provision in proposed 9 CFR 319.10(c)(3) and 381.172(c)(3) that states that ingredients specifically prohibited for use in standardized meat and poultry products should also be prohibited for use in substitute standardized products subject to the general standard. However, the commenter felt that ingredients prohibited from use in all meat and poultry products should be based on safety considerations rather than quality considerations.

Response: The general standard allows for the use of any safe and suitable fat replacement ingredient, *e.g.*, binders and water. Under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*), FDA is responsible for determining the safety of food ingredients for use in food in general. Under the authority of the FMIA and PPIA, FSIS acquiesces to FDA's safety judgments, but FSIS determines the suitability of ingredients determined to be safe by FDA for use in meat and poultry products. These responsibilities are fully described in the final rule ''Food Ingredient and Sources of Radiation Listed or Approved for Use in the Production of Meat and Poultry Products,'' which was published in the December 23, 1999, **Federal Register** (64 FR 72168).

Thus, although it is the responsibility of the FDA to evaluate the safety of a substance for use in meat or poultry products, under the authority of the FMIA and PPIA, FSIS may preclude the use of a substance in meat or poultry products for reasons other than safety. There are instances in which the use of a substance, even if safe, may promote deception when used in a meat and poultry product, and, accordingly, such use would be prohibited by FSIS. For example, paprika is considered GRAS by FDA and is also listed for use as a color additive, but the FSIS regulations prohibit its use on fresh, uncooked meat products because such use adds color that may make the meat appear fresher than it actually is (9 CFR 424.23(a)(1)). Therefore, it is incumbent upon FSIS to consider suitability, as well as the safety, of ingredients for use in the production of meat and poultry

products in order to prevent these products from being adulterated or misbranded.

Processing Methods/Anatomical Location for Meat and Poultry Ingredients

Comment: One commenter stated that the provision in proposed §§ 319.10 and 381.172 that requires that the meat portion of a substitute standardized product undergo the same basic processing procedures as the traditional standardized product for which it is a substitute has the potential to limit the use of new technologies without producing any stated goal that would justify the limitation. The commenter stated, that as long as the substitute standardized product has performance characteristics that are similar to the traditional standardized product, and is produced only from authorized ingredients, additional restrictions on processing procedures are unnecessary and undesirable.

Another commenter stated that the general standard should permit substitute standardized products to contain different meat species and different kinds of poultry than those prescribed by the traditional standard, and that it should permit meat or poultry from different anatomical locations than the locations prescribed by the traditional standard, provided that the difference in species or anatomical location is stated in the product name. This commenter felt that a literal reading of the proposed regulation could be interpreted to mean that products such as ''Beef Bacon'' or ''Pork Shoulder Bacon'' would no longer be permitted to include the term ''Bacon'' in their product names if coupled with a nutrient content claim. The commenter went on to say that these kinds of products should continue to be permitted to be marketed under the same familiar names that have been used in the past, and that use of a nutrient content claim next to the product name should not change this.

Response: The intent of the general standard for substitute standardized products is to enable the meat and poultry industries to produce modified versions of standardized products that have reductions of certain constituents that are of health concern to some consumers, such as fat, cholesterol, and sodium, and to increase flexibility and support product innovation. Under this rule, deviations from the existing standards are not expected to result in a product that no longer resembles the original standardized product. Thus, the use of a different meat species or kind of poultry, or the use of meat or poultry from different anatomic locations from those specified in the standard, that results in a product that is so physically dissimilar from the traditional standardized product that it does not meet the definition of ''substitute'' set forth in 9 CFR 317.313(d) and 381.413(d) would be inconsistent with the intent of this rule. For these kinds of products to represent themselves as substitute standardized products would be false and misleading under the FMIA and PPIA.

As an illustration, the regulatory standard for ''Bacon'' under 9 CFR 319.107 requires that this product be prepared from cured, sliced pork bellies. Curing and slicing a cut of meat from a different livestock species or from a different anatomical location, or preparing sliced pork bellies using a method other than curing, would result in a product with physical characteristics so different from the standardized product ''Bacon'' that the resulting product could not be considered a ''substitute'' for bacon under 9 CFR 317.313(d) and 381.413(d). Thus, instead of being identified as a substitute product, the product would be identified by a descriptive term such as ''Beef Bacon'' or ''Pork Shoulder Bacon.''

However, FSIS will consider the types of changes requested by the commenters, such as amending a standard to permit the use of alternative processing methods, on a case-by-case basis. FSIS agrees that certain technologies used to prepare standardized foods may yield a product with the same physical, nutritional, and sensory characteristics as the food made in accordance with the traditional standards. To reflect this fact, instead of specifying that substitute standardized products must contain all ingredients specifically required by a standard of identity or composition, and that the meat or poultry portion of substitute products come from the same anatomical location, be of the same kind and amount, and undergo the same basic processing procedures as the standardized product as was proposed, FSIS is revising §§ 319.10(c)(4) and 381.172(c)(4) to require only that substitute standardized products comply with all other applicable standards of identity or composition.

Regarding the comment expressing concern that under the general standard, products such as ''Beef Bacon'' or ''Pork Shoulder Bacon'' would no longer be permitted to include ''Bacon'' in their product names if coupled with a nutrient content claim, as previously mentioned, FSIS intends to apply the principles embodied in the general standard established by this final rule to other products as appropriate. The Agency will clarify this fact in a policy bulletin after this final rule is published.

Thus, this final regulation will not prohibit the ''bacon-like'' products described in the Policy Book, such as ''Turkey Bacon-Cured Turkey Breast Meat-Chopped and Formed,'' from being modified to qualify to use a nutrient content claim as part of the product name. The modified version of this ''bacon-like'' product would be permitted to be identified as ''Low Fat Turkey Bacon-Cured Turkey Breast Meat-Chopped and Formed.'' FSIS reiterates that the intent of this rule is to provide a wider array of nutritionally improved substitute products that would provide consumers with more meat and poultry products from which to choose. The intent is not to diminish or interfere with markets providing innovative as well as traditional kinds of products to consumers.

Minimum Meat and Poultry Requirement

Comment: Several commenters submitted statements both for and against the proposed requirement that a substitute standardized product subject to the general standard rule maintain the same minimum meat or poultry requirement as the standardized product for which it is a substitute. Seven commenters agreed that substitute standardized products should be required to maintain the minimum meat and poultry requirement established by the traditional standard, while ten commenters expressed disagreement with this requirement.

Several commenters stated that the meat or poultry content of a standardized product often contains the highest concentration of fat, and, while it may be theoretically possible for manufacturers to use leaner meat to reduce fat, it is not economical. One of these commenters stated that fat-reduced products that meet the existing minimum meat or poultry content requirement would be prohibitively expensive. Another commenter stated that relying exclusively on leaner meat to reduce fat might also make products tougher in texture and less palatable. Another commenter stated that, without reducing the ''meat block'' (meat or poultry content), the proposed general standard can not deliver on its promise to encourage innovation and the production of nutritionally improved meat and poultry products.

Some commenters stated that minimum meat and poultry content requirements for substitute products are not necessary so long as the labeling of

the substitute standardized products provides sufficient information to distinguish these products from the traditional standardized products for which they substitute. One commenter submitted data showing that consumers do not mind if part of the meat block in a substitute product is replaced with another ingredient, so long as the labeling of the substitute standardized product discloses the presence of the replacing ingredient. Another commenter stated that trends in consumer behavior, which include reducing the amount of meat consumed in order to reduce fat intake, strongly support the argument that consumers will not be misled by nutrient-modified food products that contain less meat and poultry than is required by the traditional standardized form of the food. One commenter suggested that a substitute standardized product with reductions in its meat or poultry content should state on its label that, ''in order to reduce fat, this product contains less meat than the traditional standardized product.'' Some commenters stated that nutritional equivalency, rather than meat-content equivalency, should serve as the basis for defining requirements for the use of nutrient content claims. These commenters felt that FSIS should allow for necessary reductions in meat or poultry content to meet the requirements of the claim, with the reduction accomplished in such a manner that nutritional equivalency to the traditional standardized product is maintained. One commenter stated that meat replacers may be more desirable than some of the fat replacers, which hold water but contribute little in taste or nutritional value.

One commenter stated that it is widely recognized that the requirements for minimum meat content are based on the notion that meat and poultry represented the most valuable constituent of a meat or poultry product. This commenter claimed that meat and poultry are simply no longer the indisputable ''highest value'' components of food products. Another commenter mentioned that FDA regulations provide for marketing of products, such as reduced-fat peanut butter, which allows for reduction of the peanut content of the product below that required for the standardized product.

Those commenters that agreed with the requirement that substitute standardized products subject to the general standard maintain the same minimum meat and poultry requirement as the standardized product for which they are a substitute maintained that consumers have come to expect a certain amount of meat or poultry in products that bear a standardized term, and that the meat and poultry content of the product is still the most valued constituent.

Response: Because many consumers have come to expect a certain amount of meat or poultry in products that bear a standardized term, deviations in the prescribed meat or poultry content will not be permitted in this final rule. Moreover, while FSIS appreciates these comments, the Agency does not view this rulemaking as the appropriate vehicle for changing the specific meat and poultry content requirements of meat and poultry product standards. These issues will be considered in a separate rulemaking that will examine FSIS's overall regulatory approach to standardized meat and poultry products that was described in the ANPR ''Meat and Poultry Standards of Identity and Composition'' published in the September 9, 1996, edition of the **Federal Register** (61 FR 47453).

In response to that ANPR, FSIS and FDA are jointly working on a more comprehensive approach to modernizing food standards whose goal is to establish ''general principles'' that interested parties could follow in requesting changes to food standards. One change that interested parties may be able to pursue, if these principles are adopted, would be reductions in the meat or poultry content requirements of standardized products. FSIS and FDA expect to soon publish the joint proposed rule in the **Federal Register**.

Nomenclature-Labeling of Nutrient Content Claims

Comment: Of those who commented, all agreed that the name of a substitute standardized product subject to the general standard should be an expressed nutrient content claim in conjunction with (*i.e.*, next to) the appropriate standardized term, as provided in the proposal. However, several commenters did not agree with the provision in proposed 9 CFR 319.10(d) and 9 CFR 381.172(d) that states that the nutrient content claim and standardized term should be presented ''in the same style, color, and size of type on the product label.''

One commenter stated that it was unaware of any evidence that consumers are confused or misled by the labels currently in the marketplace on similar FDA-regulated products, which are not subject to a style, color, and size of type requirement. The commenter stated that the 3:1 type size requirement that generally applies to names on FSIS-regulated products should apply to foods that are marketed under the general standard rule.

Another commenter stated that some flexibility should be allowed for the type size of the nutrient content claim. The commenter stated that some product names are fairly lengthy, and therefore, FSIS's Policy Memo 87A , *Word Size in Labeling of Product Names and Fanciful Names*, states that the Agency will not object to a ⅓ type size flexibility between the largest letter and the smallest letter in a product name. The commenter also noted that the existing FSIS regulations for nutrient content claims allow a ½ type size flexibility to assure that nutrient claims are not disproportionately larger than the product's statement of identity.

Two commenters stated that the FDA regulation establishing a general standard for FDA-regulated substitute standardized products (21 CFR 130.10(e)) does not contain the same restrictions on the style, color, and size of type of the nutrient content claim that FSIS's proposed rule does. One of these commenters requested that FSIS consider modifying the proposed nomenclature for products subject to its general standard to make it similar in format to that prescribed by the FDA regulation. A similar comment suggested that FSIS delete the last clause from the nomenclature section, *i.e.*, '' * * * which shall be in the same style, color, and size of type,'' because it is unwarranted and unnecessary to inform consumers of the nature of the substitute product.

Response: FSIS agrees with the commenters' arguments and in this final rule has deleted the last clause from the nomenclature section (''* * * which shall be in the same style, color, and size of type''). FSIS has been persuaded by the arguments against requiring the nutrient content claim portion of the substitute standardized product's name to be presented in the same style, color, and size of type, as the standardized product term and agrees that this requirement is unnecessary for consumers to distinguish the substitute product from other products that bear nutrient content claims but that are not substitute products that meet the requirements of this final rule. Therefore, to harmonize, to the extent possible, its labeling requirements with the labeling requirements of FDA's corresponding regulations found in 21 CFR 130.10, FSIS will not require that the expressed nutrient content claim that is part of the product identity appear in ''the same style, color, and size of type'' as the standardized term. The product name on the principal display panel of the substitute product,

as well as its ingredients statement, are the pertinent labeling features that identify the differences between the traditional standardized product and the modified version bearing the standardized name.

Ingredient Labeling

Comment: Twenty commenters expressed agreement with the provision in proposed 9 CFR 319.10(e) and 381.172(e) that all safe and suitable ingredients not provided for by the traditional standard, as well as permitted ingredients added at a level in excess of those allowed by the traditional standard, must be appropriately identified as such with an asterisk in the ingredients statement. Three commenters disagreed.

Two commenters stated that because a nutrient content claim calls the consumer's attention to the fact that the product has been modified from the traditional standardized product, there is no need for asterisks to be included in the labeling information. These commenters believed that the product name with the appropriate nutrient content claim, along with the ingredients statement, is all that is necessary to adequately inform the consumer that the product has been modified from the traditional standard. One commenter stated that, in addition to adding to label clutter, the requirement to highlight ingredients present in amounts greater than in the standardized product could result in the ''ludicrous'' situation where a label indicates that the substitute product contains more meat than the traditional standardized product. The commenter felt that requiring an asterisks for particular ingredients will provide a disincentive for meat and poultry processors to make products using the new technologies in fat replacement products because they must market products with labels that are cluttered with additional statements.

One commenter expressed support for using an asterisk to identify ingredients not provided for, or used in excess of those levels provided for, by the traditional standard in so far as it provides parity with FDA's regulation but questioned the real value of this labeling feature to the consumer. The commenter suggested that this labeling requirement be applicable on a short-term basis, with provisions for its phase-out in no more than three years as consumer become more familiarly with nutritionally-modified foods.

Two commenters felt that FSIS should require more than just the identification of the substitute ingredients in the ingredients listing, as proposed by the Agency. These commenters suggested that FSIS also require that whenever ingredients are present in the substitute product that are not permitted by the traditional product standard, an appropriate disclosure (*e.g.* ''made with non-standard ingredients—see back panel for ingredient lists'') appear on the principal display panel. One of these commenters stated that such a disclosure would alert consumers to the fact that a substitute product is different from the standardized product and would direct them to specific information about the differences.

Several commenters requested that FSIS clarify whether the ingredient ''water'' or the added moisture not normally in or in excess of that permitted in a standardized product should be indicated with an asterisk.

Response: FSIS disagrees with the comment that ingredients not provided for by the traditional standard, as well as permitted ingredients added at a level in excess of those allowed by the traditional standard, need not be identified as such with an asterisk in the ingredients statement. Differences between the ingredients in a standardized product and a substitute standardized product identified in part by a nutrient content claim must be highlighted so that consumers will be able to differentiate between the traditional standardized product and the substitute version. Highlighting these ingredient differences also ensures that the labeling of the substitute product will not be misleading. Furthermore, as a point of clarification, when water or added moisture not found in or used in excess of that permitted in a traditional standardized product is added to a substitute standardized product, this fact must be highlighted with an asterisk as is required for all other safe and suitable ingredients not found in, or used in excess of, the amount permitted by the traditional standard.

FSIS disagrees with the comment that requiring an asterisks to highlight specific ingredients present in a substitute standardized product will provide a disincentive for meat and poultry processors to make and manufacture standardized products with reductions in their fat content. Similar labeling has been required on FDA-regulated products for several years and does not appear to have been a disincentive for industry to develop these kinds of products. FSIS also disagrees that labeling features in addition to those provided in the proposed rule are necessary to inform consumers of ingredient differences between a traditional standardized product and its nutritionally modified substitute. Highlighting ingredient differences with an asterisk in the ingredients statement, along with the product name on the principal display panel, are the pertinent labeling features that identify the differences between the traditional standardized product and the substitute version. Furthermore, to some consumers, statements such as ''made with non-standard ingredients'' may imply that the ingredients used in a substitute product are inferior or harmful to the ingredients used in the traditional standardized product. Such statements could be misleading because only ingredients that have been found to be safe and suitable for use in meat and poultry products are permitted to be used in formulating substitute standardized products.

Consumers who have purchased substitute standardized products manufactured pursuant to FDA's general standard codified at 21 CFR 130.10 are familiar with the labeling of such products through the use of asterisks and the statement referenced by the asterisks, which appear adjacent to the ingredient list. Thus, many consumers already look to the ingredient statement to determine differences in formulation between traditional standardized products and nutritionally modified versions of these products. Harmonizing labeling to the extent possible with that of the FDA benefits consumers by providing a more consistent food labeling system across all foods.

FSIS finds no merit in the comment that asterisks are unnecessary because they could lead to the ''ludicrous'' situation where an ingredients statement asterisk would indicate that more meat or poultry than required by the food standard has been used in the product. Because food standards for meat and poultry products generally require minimum amounts of meat and poultry and maximum amounts of fat and water, it has always been possible for manufacturers to include more meat or poultry than the minimum established by the food standard in the product formulation. This rule does not change that fact and there is no need to require an asterisk to highlight the fact that a manufacture chose to include more meat or poultry in a substitute product than the minimum required by the traditional standard.

Regarding the comment that the asterisk provision should be phased out at some point in the future, FSIS does not agree with this view because the ingredient statement is the primary feature where the differences between the standardized product and the substitute version can be made known to the consumer in labeling. As

described earlier, during the joint FSIS and FDA standards modernization activities, if appropriate, the agencies may revisit the issue of phasing out the asterisk requirement and consider it within the context of a more comprehensive approach to food standards modernization.

The Final Rule

In this final rule, FSIS is establishing a general definition and standard of identity for standardized meat and poultry products that have been modified to qualify for use of an expressed nutrient content claim in their product names in conjunction with a standardized term. FSIS is adding new §§ 319.10 and 381.172 to the meat and poultry products regulations in title 9 of the CFR. As was proposed, §§ 319.10(a) and 381.172(a) describe the type of meat and poultry products that are defined by the general standard. These are products that substitute, in accordance with 9 CFR 317.313(d) or 381.413(d), for a standardized product, but that do not comply with the established standard because of a compositional deviation that results from reductions of a constituent that is described by an express nutrient content claim, such as ''low fat'' or ''fat free.''

As was proposed, §§ 319.10(b) and 381.172(b) require that a substitute standardized product subject to the general standard have similar performance characteristics to the traditional standardized product for which it is a substitute. However, if a substitute product has performance characteristics that materially limit the uses of the product compared to the uses of the traditional standardized product, §§ 319.10(b) and 381.172(b) require that a product's label include a disclaimer informing consumers of such differences, such as ''not suitable for grilling.'' In response to some of the comments and to be consistent with the existing definition of substitute products found in 9 CFR 317.313 and 381.413, FSIS is removing the provision in proposed §§ 319.10(b) and 381.172(b) that would have required the performance characteristics disclaimer to appear ''adjacent to the product name.'' Deleting this provision is also intended to provide consistency with 21 CFR 130.10 of the FDA regulations, which is the codified general standard of identity for substitute standardized products under FDA jurisdiction. As was proposed, §§ 319.10(b) and 381.172(b) will require that deviations in the ingredients in a substitute standardized product be the minimum necessary to qualify for the nutrient content claim.

Sections 319.10(c) and 381.172(c) prescribe the ingredients that must be used in, and the ingredients that are permitted to be used in, substitute standardized products under the general standard. As was proposed, §§ 319.10(c)(1) and 381.172(c)(1) require that the ingredients used in a substitute standardized product be those ingredients provided for by the traditional standard, except that in addition, safe and suitable ingredients may be used in the substitute product at the minimum level necessary to improve texture or prevent synereses. The final rule replaces references to former §§ 318.7 and 381.147 with the phrase ''as provided in a regulation permitting that use in this subchapter or in 9 CFR Chapter III, Subchapter E, or in 21 CFR Chapter I, Subchapter A or Subchapter B,'' to reflect the issuance of the final rule ''Food Ingredients and Sources of Radiation Listed or Approved for Use in Meat and Poultry Products'' (64 FR 72168).

As was proposed, §§ 319.10(c)(2) and 381.172(c)(2) forbid substitute standardized products to replace or exchange ingredients required by the traditional standard with functionally similar ingredients from other sources not provided for in the traditional standard. In the final rule, FSIS is removing the phrases ''textured vegetable protein shall not replace meat'' and ''textured vegetable protein shall not replace poultry'' from proposed §§ 319.10 (c)(2) and 381.172(c)(2). These phrases are unnecessary and could potentially cause confusion since the final rule permits TVP to be used in limited amounts as a fat replacer, although it may not be used to replace meat. Reductions in the meat or poultry content required by the traditional standard are already prohibited by the final rule regardless of whether TVP is used in the product.

As was proposed, §§ 319.10(c)(3) and 381.172(c)(3) prohibit substitute standardized products from containing ingredients that are prohibited for use in traditional standardized products. Proposed §§ 319.10(c)(2) and(3), and 381.172(c)(2) and (3) use the phrase ''[a]n ingredient or component of an ingredient'' when describing the ingredients permitted and prohibited in substitute standardized products. In this final rule, FSIS is deleting the words ''or component of an ingredient'' because they are unnecessary and may cause confusion.

Proposed, §§ 319.10(c)(4) and 381.172(c)(4) required substitute standardized products to conform to certain aspects of the traditional standard, such as the meat or poultry content specified in the standard, the anatomic location and kind of meat or poultry specified in the standard, and the processing procedures specified in the standard. As previously mentioned, deviations from these types of requirements may result in a product that is so physically dissimilar from the traditional standardized product that it does not come within the established definition of a substitute product.

However, because certain technologies used to prepare standardized foods may yield a product with the same physical, nutritional, and sensory characteristics as the food made in accordance with the traditional standards, FSIS intends to consider certain deviations from product standards, such as alternative processing methods, on a case-by-case basis. As stated above, FSIS and FDA are jointly working on a more comprehensive approach to modernizing food standards to establish ''general principles'' that interested parties would follow in requesting changes to or creating new food standards. Therefore, FSIS is revising proposed §§ 319.10(c)(4) and 381.172(c)(4) to require that substitute standardized products comply with all other applicable standards of identity or composition unless otherwise specified in part 319 or part 381. The Agency is making this revision to accommodate changes to food standards that may result from the joint FSIS/FDA food standards modernization approach.

As was proposed, §§ 319.10(c)(5) and 381.172(c)(5) permit water and fat-replacing binders to be used to reduce the fat content in a substitute standardized product subject to the general standard. Based on the comments and data submitted in response to the proposal in support of using TVP as a ''fat replacer,'' FSIS will permit the use of TVP as a functional fat replacing ingredient in substitute standardized products defined by the general standard. FSIS is adding new language to the final rule that permits the use of TVP as part of a fat replacement system at the lowest level necessary to achieve the technical effect of replacing the characteristics of fat in the substitute product. This language is found in new §§ 319.10(c)(6) and 381.172(c)(6). Because §§ 319.10(c)(2) and 381.172(c)(2) of the final rule forbid reductions in the meat or poultry content of a substitute product where one is established by a standard, under the final rule, TVP may only be used to replace fat component and not to replace the lean meat or poultry content of the substitute standardized product.

Sections 319.10(d) and 381.172(d) prescribe the nomenclature for the substitute meat and poultry products that comply with the general standard. As was proposed, these products may be identified by the appropriate expressed nutrient content claim and the applicable standardized term (*e.g.*, ''Fat Free Bologna''). If a product meets the requirements of the general standard, it is itself a standardized product, and therefore, its name will not be required to contain the term ''substitute'' despite the fact that it does not meet all of the requirements of the traditional product standard.

This final rule removes the provisions in proposed §§ 319.10(d) and 381.172(d) that would have required that the expressed nutrient content claim part of the substitute standardized product's name appear in the ''same style, color and size type'' as the standardized term. This change is in response to public comments and to harmonize, to the extent possible, with similar FDA regulations.

As was proposed, §§ 319.10(e) and 381.172(e) require each of the ingredients used in the substitute product to be declared on the product label as required by the applicable FSIS regulations. 9 CFR parts 317 and 381, subpart N, require that all ingredients be listed by common or usual name in descending order of predominance by weight. As was proposed, §§ 319.10(e) and 381.172(e) also require that all safe and suitable ingredients not provided for by the traditional standard, as well as those used in excess of those permitted by the traditional standard, be identified as such with and asterisks in the ingredients statement.

Executive Order 12866 and Regulatory Flexibility Act

This rule has been determined to be significant and therefore has been reviewed by OMB under EO 12866.

I. Need for the Rule

FSIS is issuing this rule to facilitate the development and availability of substitute standardized products that have reductions in certain constituents that are of health concern to some consumers, such as fat, cholesterol, and sodium. This rule allows FSIS to rely more on labeling requirements and less on restrictive recipe-like standards in endeavoring to ensure that the labels of meat and poultry products are truthful and not misleading as well as to improve the public health. The names of products covered by the General Standard will be composed of an express nutrient content claim that reflects the modifications made in formulating and processing the product (so that it qualifies to bear the claim) and an established standardized term. FDA has already promulgated a corresponding General Standard for the products that it regulates (21 CFR 130.10). By harmonizing an FSIS labeling requirement with that of FDA, this final rule represents a significant step towards providing consumers with an informative and consistent food standard and labeling system. This final rule also promotes product innovation by encouraging the production of meat and poultry products that are low in constituents that are of health concern to some people.

II. Description of Affected Industry

FSIS regulations contain approximately 80 standards of identity or composition for meat and poultry products. Most of these standards are for processed products, including sliced, injected, smoked, fermented, heat-treated, and raw products. According to the Agency's Performance Based Inspection System Database, in the second quarter of 2003, there were approximately 6,600 Federal and State Establishments [2] that potentially will be affected by the final rule if they develop and make available substitute products for standardized products. Some of these establishments, however, are already producing sausage and other comminuted meat and poultry products under FSIS Policy Memo 121B and Policy Memo 123 which provide for the type of substitute products defined under this final rule. Thus, this rule is likely to have little or no impact on the processing establishments that are producing products in accordance with the policy memos.

Ingredient manufacturers who produce binders and textured (source) protein products (*e.g.*, textured soy or wheat protein) will be affected by the final rule because the rule will permit the increased use of these ingredients as fat replacing ingredients in some modified standardized products.

III. Costs

The decision to produce products subject to the General Standard established by this rule is voluntary. Therefore, only those manufacturers that choose to produce and market these products will incur the direct costs imposed by this rule. These costs include research and development, production and marketing, and labeling production. However, because the rule is voluntary, companies that choose to produce products covered by the General Standard will do so only if they determine that the benefits of producing and selling these products outweigh the costs of complying with the final rule. Furthermore, companies that are already producing and marketing products under Policy Memo 121B and Policy Memo 123 (*i.e.*, comminuted meat and poultry products) are likely to incur minimal or no costs as a result of this final rule.

Under most circumstances, companies are likely to charge a premium for substitute standardized product produced in compliance with this final rule because many consumers will be willing to pay a premium for products with improved nutritional profiles. They view these products as ''value added'' products.[3] Therefore, based on the experience of food companies that are operating under FDA's 21 CFR 130.10 regulations, *e.g.*, the manufacturers of fat-free ice cream and reduced fat cream cheese, any costs associated with producing and marketing substitute products most likely will be passed on to the consumer in the form of higher retail prices.

However, once this rule becomes effective, some companies that are not producing substitute meat and poultry products under Policy Memo 121B or Policy Memo 123 may begin to manufacture and market substitute standardized products in accordance with the General Standard because of the market value of using traditional product names. Their decision to do so could have the effect of increasing the supply of these types of products in the short run, which could translate into lower prices for consumers.

IV. Benefits

This rule will assist consumers in making dietary choices by providing for modified versions of standardized meat and poultry products that have reductions of certain constituents that are of health concern to some consumers, such as fat, cholesterol, and sodium. Therefore, there will be a greater opportunity for consumers to maintain or to initiate healthy dietary practices. In the United States, diets high in fat, cholesterol, and sodium are associated with chronic diseases such as coronary heart disease, cancer, stroke, and diabetes. In 2002, according to the Centers for Disease Control National Center for Chronic Disease Prevention and Health Promotion, 7 out of every 10 U.S. deaths and more than 60% of medical care expenditures are attributed to chronic diseases. In addition, the

[2] These establishments processed, froze, stored, or otherwise held meat and poultry products.

[3] Consumer purchasing trends.

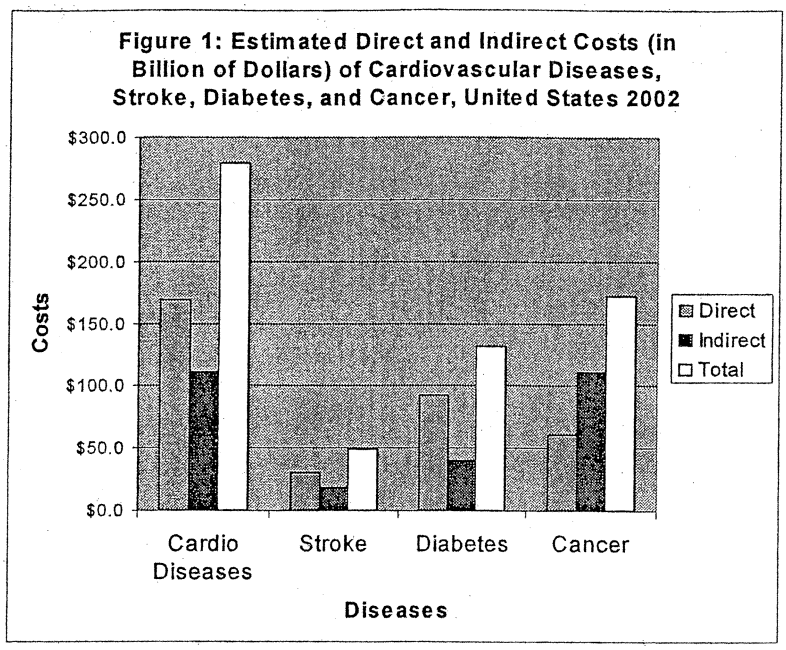
prolonged illness and disability associated with many chronic diseases decrease the quality of life for millions of consumers.

ESTIMATED DIRECT AND INDIRECT COSTS OF CARDIOVASCULAR DISEASES, STROKE, DIABETES, AND CANCER IN THE UNITED STATES—2002

[In Billion of Dollars]

Costs	Cardiovascular diseases	Stroke	Diabetes	Cancer
Direct	$168.7	$30.8	$92.0	$61.0
Indirect	111.1	18.6	40.0	111.0
Total	279.8	49.4	132.0	172.0

According to the 2002 Heart and Stroke Statistical Update published by the American Heart Association and the American Stroke Association, the total cost of cardiovascular diseases and strokes in the United States was estimated at $279.8 billion and $49.4 billion, respectively, as reflected in the above table and figure 1 below. Direct costs ($168.7 billion and $30.8 billion, respectively) consist of the cost of physicians and other health professionals, hospital and nursing home services, medication, home health care, and other medical durables. Indirect costs ($111.1 billion and 18.6 billion, respectively) consist of lost productivity resulting from morbidity and mortality.



The total cost in 2002 associated with diabetes was $132 billion of which $92 billion were direct costs and $40 billion were indirect costs.[4] The estimated total costs for all cancers in 2002 were $172 billion ($61 billion in direct costs and $110 billion in indirect costs)[5].

Most chronic diseases are preventable, or their onset can be delayed, through increased physical activity and healthy eating. There is research to support that practicing good nutrition lowers the risk of chronic diseases for many consumers.[6] The total estimated cost of chronic diseases to the consumer is $633.2 billion. The extent to which these costs might be reduced by an improved diet cannot be calculated precisely, but some researchers estimate that a balanced and healthful diet might forestall at least 20 percent of the annual deaths from heart disease, stroke, cancer, and diabetes.[7]

It is reasonably expected that the final rule could contribute to the reduction of these costs, but this contribution, too, cannot be calculated precisely. In the ''Economic Benefits of Nutrition Labeling: A Case Study for Fresh Meat and Poultry Products,'' the Agency estimated the potential benefits of reducing the incidence of coronary heart disease and three types of cancers at $61.8 million, (7 percent discount rate); and $125 million (3 percent discount rate).[8]

The results of the 2002 ''Trends'' survey'' conducted by the Food

[4] ''The Economic Costs of Diabetes in the U .S. 2002'', American Diabetes Association.

[5] Heart Disease and Stroke Statistics—2003 Update, American Heart Association.

[6] CDC National Center for Chronic Disease Prevention and Health Promotion, ''Physical Activity and Good Nutrition: Essential Elements to Prevent Chronic Diseases and Obesity.''

[7] ''The American Diet: A Costly Health Problem, Food Review.''

[8] The Agency estimated the potential benefit of an FSIS rule (2001). Nutrition Labeling of ground or chopped meat and poultry products and single-ingredient products. **Federal Register**, 66, 4969–4999.

Marketing Institute (*Trends in the United States, Consumer Attitudes and the Supermarket*) stated that 80 percent of consumers surveyed indicated that they had sought out and purchased products based on ''low-fat'' claims; 60 percent had purchased products because of ''low cholesterol'' claims; 59 percent purchased products because of ''natural'' claims; and 52 percent purchased products because of ''low salt'' claims. If this trend continues, and the final rule is promulgated, it is more than likely that the final rule will assist in the reduced incidence of chronic diseases by expanding the availability of meat and poultry products with lower levels of constituents such as fat, cholesterol, and sodium.

In conclusion, this final rule will assist consumers who want to reduce their dietary intake of fat, cholesterol, and sodium by encouraging the production of modified versions of traditional meat and poultry products that are formulated with fat, cholesterol, and sodium-replacing ingredient systems that reduce these constituents. The final rule will provide parity with FDA's regulations and will promote a unified approach to food standards and labeling. Most importantly, the final rule supports national efforts to reduce the expenditures for health care and the cost of morbidity and lost productivity by permitting the introduction of modified, substitute foods.

In terms of administrative benefits, the General Standard established by this final rule will permit industry to introduce modified, substitute versions of traditional standardized meat and poultry products without having to petition FSIS to establish new standards for products on a case-by-case basis. This will generate efficiency within the food standards system by saving time and resources that would have been expended by both the industry and FSIS to establish new or modified product standards. It will also permit companies to introduce standardized meat and poultry products with improved nutritional profiles into the marketplace in a timely manner, making such products more readily available to consumers.

V. Regulatory Flexibility Analysis

The FSIS Administrator has made a final determination that this rule will not have a significant economic impact on a substantial number of small entities, as defined by the Regulatory Flexibility Act (5 U.S.C. 601).

This final rule will not impose any new requirements on small entities. The decision to produce versions of standardized products that have been modified to qualify for use of an expressed nutrient content claim in conjunction with a traditional product name is voluntary. Therefore, the requirements of this final rule will only apply to those small manufacturers who choose to produce these types of products. Those small entities that choose to produce these products will be required to design new labels or to revise current labels to comply with this new rule, and thereby incur some costs. However, small entities who will be marketing these substitute products will most likely have anticipated that the revenues generated from the sale of these products will outweigh the costs of complying with the new regulation.

Executive Order 12988

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. This final rule: (1) Preempts State and local laws and regulations that are inconsistent with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule. However, the administrative procedures specified in 9 CFR 306.5, 381.35, and 590.320 through 590.370 must be exhausted before any judicial challenge of the application of the provisions of this rule, if the challenge involves any decision of an FSIS employee relating to inspection services provided under the FMIA or PPIA.

Paperwork Reduction Act

In accordance with section 3507(j) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), FSIS will submit the information collection and recordkeeping requirements in this final rule to the Office of Management and Budget (OMB) for approval.

Title: Food Standards: Requirements for Substitute Standardized Meat and Poultry Products Named by Use of an Expressed Nutrient Content Claim and a Standardized Term.

Type of collection: New.

Abstract: Under this final rule, FSIS is requiring that establishments that produce meat and poultry products in accordance with the definition and general standard of identity for substitute standardized products design new product labels and submit sketches of the new labeling to FSIS for approval. To receive approval of the labels, establishments must complete FSIS form 7234–1. FSIS employees review FSIS form 7234–1 to ensure that information on the labels complies with the regulations.

Estimate of burden: FSIS estimates that it will take 60 minutes to design and develop modified product labels in accordance with the final regulations and 15 minutes to prepare FSIS form 7234–1 and submit it, along with the label, to FSIS.

Respondents: Establishments that produce substitute standardized meat or poultry products in accordance with this final rule.

Estimated Number of Respondents: 100.

Estimated Number of Responses per Respondent: 5.

Estimated Total Annual Burden on Respondents: 625 hours.

Copies of this information collection assessment can be obtained from John O'Connell, Paperwork Reduction Act Coordinator, Food Safety and Inspection Service, USDA, 112 Annex, 300 12th Street, SW., Washington, DC 20250. Comments are invited on (a) Whether the 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 Agency's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected, ways to minimize 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. Comments may be sent to both John O'Connell, Paperwork Reduction Act Coordinator, at the address provided above, and the Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20253. To be most effective, comments should be sent to OMB within 30 days of publication.

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, in an effort to ensure that the public and in particular minorities, women, and persons with disabilities, are aware of this final rule, FSIS will announce it on-line through the FSIS Web page located at *http://www.fsis.usda.gov/regulations_&_policies/2005_Interim_&_Final_Rules_Index/index.asp.* The Regulations.gov Web site is the central online rulemaking portal of the United States government. It is being offered as a public service to increase participation in the Federal government's regulatory activities. FSIS participates in Regulations.gov and will

accept comments on documents published on the site. The site allows visitors to search by keyword or Department or Agency for rulemakings that allow for public comment. Each entry provides a quick link to a comment form so that visitors can type in their comments and submit them to FSIS. The Web site is located at *http://www.regulations.gov/.*

FSIS also will make copies of this **Federal Register** publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, recalls, and other types of information that could affect or would be of interest to our constituents and stakeholders. The update is communicated via Listserv, a free e-mail subscription service consisting of industry, trade, and farm groups, consumer interest groups, allied health professionals, scientific professionals, and other individuals who have requested to be included. The update also is available on the FSIS Web page. Through Listserv and the Web page, FSIS is able to provide information to a much broader, more diverse audience.

In addition, FSIS offers an email subscription service which provides an automatic and customized notification when popular pages are updated, including **Federal Register** publications and related documents. This service is available at *http://www.fsis.usda.gov/news_and_events/email_subscription/* and allows FSIS customers to sign up for subscription options across eight categories. Options range from recalls to export information to regulations, directives and notices. Customers can add or delete subscriptions themselves and have the option to password protect their account.

List of Subjects

9 CFR Part 319

Food grades and standards, Meat inspection.

9 CFR Part 381

Food grades and standards, Meat inspection, Poultry and poultry products.

■ For the reasons stated in the preamble, FSIS amends 9 CFR parts 319 and 381 as follows:

PART 319—DEFINITIONS AND STANDARDS OF IDENTITY OR COMPOSITION

■ 1. The authority citation for part 319 continues to read as follows:

Authority: 7 U.S.C. 450, 1901–1906; 21 U.S.C. 601–695; 7 CFR 2.18, 2.53.

■ 2. Part 319, subpart A is amended by adding a new § 319.10 to read as follows:

§ 319.10 Requirements for substitute standardized meat food products named by use of an expressed nutrient content claim and a standardized term.

(a) *Description.* The meat food products prescribed by this general definition and standard of identity are those products that substitute, in accordance with § 317.313(d), for a standardized product defined in this part and use the name of that standardized product in their statements of identity, but that do not comply with the established standard because of a compositional deviation that results from reduction of a constituent that is described by an expressed nutrient content claim that has been defined by regulation in part 317, subpart B, of this subchapter. The expressed nutrient content claim shall comply with the requirements of § 317.313 of this subchapter and with the requirements of part 317, subpart B, of this subchapter which define the particular nutrient content claim that is used. The meat food product shall comply with the relevant standard in this part in all other respects, except as provided in paragraphs (b) and (c) of this section.

(b) *Performance characteristics.* The performance characteristics, such as physical properties, functional properties, and shelf-life, of the meat food product shall be similar to those of the standardized meat food product produced under this part. If there is a significant difference in a performance characteristic that materially limits the use of the product compared to the use of the standardized product defined in this part, the label shall include a statement in accordance with § 317.313(d)(1) and (2) of this subchapter that informs the consumer of such differences (*e.g.*, if appropriate, ''not recommended for frozen storage'' or ''not suitable for roller grilling''). Deviations from the ingredient provisions of the standard must be the minimum necessary to qualify for the nutrient content claim, while maintaining similar performance characteristics.

(c) *Ingredients used in substitute products.* (1) Ingredients used in the product shall be those ingredients provided for in the standard as defined in this part, except that safe and suitable ingredients permitted for use in meat food products as provided in a regulation permitting that use in this subchapter or in 9 CFR Chapter III, Subchapter E, or in 21 CFR Chapter I, Subchapter A or Subchapter B, may be used at the minimum level necessary to improve texture and prevent syneresis, so that the substitute product is not inferior in performance characteristics from the standardized product defined in this part for which it is a substitute.

(2) An ingredient that is specifically required by the standard prescribed in this part shall not be replaced or exchanged with a similar ingredient from another source, for example, turnip chunks shall not replace potatoes in corned beef hash.

(3) An ingredient that is specifically prohibited from use in any meat food product by this part shall not be added to the substitute meat food product under this section.

(4) Unless otherwise specified in this part, a substitute meat food product must meet all other requirements of the applicable standards of identity or composition.

(5) Water and fat-replacers (*e.g.*, binders), in combination, may be added to replace fat in accordance with paragraph (c) of this section.

(6) Textured vegetable protein may be used by itself or in combination with other binders and water as a fat replacer in accordance with paragraph (c) of this section.

(d) *Nomenclature.* The name of a substitute meat food product that complies with all parts of this section is the appropriate expressed nutrient content claim and the applicable standardized term.

(e) *Label declaration.* (1) Each of the ingredients used in the substitute meat food product shall be declared on the label as required by this section and part 317 of this subchapter.

(2) Ingredients not provided for, and ingredients used in excess of those levels provided for, by the standard as defined in this part, shall be identified as such with an asterisk in the ingredients statement. The statement ''*Ingredients not in regular _____'' (the blank shall be filled in with the name of the traditional standardized product) or ''**Ingredients in excess of amounts permitted in regular _____'' (the blank shall be filled in with the name of the traditional standardized product), or both, as appropriate, shall immediately follow the ingredients statement in the same type and size.

PART 381—POULTRY PRODUCTS INSPECTION REGULATIONS

■ 3. The authority citation for part 381 would continue to read as follows:

Authority: 7 U.S.C. 138f; 450, 21 U.S.C. 451–470, 7 CFR 2.18, 2.53.

■ 4. Part 381, subpart P is amended by adding a new § 381.172 to read as follows:

§ 381.172 Requirements for substitute standardized poultry products named by use of an expressed nutrient content claim and a standardized term.

(a) *Description.* The poultry products prescribed by this general definition and standard of identity are those products that substitute, in accordance with § 381.413(d), for a standardized product defined in this subpart and use the name of that standardized product in their statements of identity, but that do not comply with the established standard because of a compositional deviation that results from reduction of a constituent that is described by an expressed nutrient content claim that has been defined by regulation in this subpart. The expressed nutrient content claim shall comply with the requirements of § 381.413 and with the requirements in subpart Y of this part which define the particular nutrient content claim that is used. The poultry product shall comply with the relevant standard in this part in all other respects, except as provided in paragraphs (b) and (c) of this section.

(b) *Performance characteristics.* The performance characteristics, such as physical properties, functional properties, and shelf-life, of the poultry product shall be similar to those of the standardized poultry product produced under subpart P of this part. If there is a significant difference in a performance characteristic that materially limits the use of the product compared to the use of the standardized product defined in subpart P of this part, the label shall include a statement in accordance with § 381.413(d)(1) and (2) of this part, that informs the consumer of such differences (*e.g.*, if appropriate, ''not recommended for frozen storage'' or ''not suitable for roller grilling''). Deviations from the ingredient provisions of the standard must be the minimum necessary to qualify for the nutrient content claim, while maintaining similar performance characteristics.

(c) *Ingredients used in substitute products.* (1) Ingredients used in the product shall be those ingredients provided for in the standard as defined in subpart P of this part, except that safe and suitable ingredients permitted for use in poultry products as provided in a regulation permitting that use in this subchapter or in 9 CFR Chapter III, Subchapter E, or in 21 CFR Chapter I, Subchapter A or Subchapter B, may be used at the minimum level necessary to improve texture and prevent syneresis, so that the substitute product is not inferior in performance characteristics from the standardized product defined in subpart P of this part for which it is a substitute.

(2) An ingredient that is specifically required by the standard prescribed in subpart P of this part shall not be replaced or exchanged with a similar ingredient from another source, for example, extruded turnips shall not replace noodles in poultry with noodles.

(3) An ingredient that is specifically prohibited from use in any poultry product by subpart P of this part shall not be added to the substitute poultry product under this section.

(4) Unless otherwise specified in this part, a substitute poultry product must meet all other requirements of the applicable standards of identity or composition.

(5) Water and fat-replacers (*e.g.*, binders), in combination, may be added to replace fat in accordance with paragraph (c) of this section.

(6) Textured vegetable protein may be used by itself or in combination with other binders and water as a fat replacer in accordance with paragraph (c) of this section.

(d) *Nomenclature.* The name of a substitute poultry product that complies with this section is the appropriate expressed nutrient content claim and the applicable standardized term.

(e) *Label declaration.* (1) Each of the ingredients used in the substitute poultry product shall be declared on the label as required by this section and subpart N of this part.

(2) Ingredients not provided for, and ingredients used in excess of those levels provided for, by the standard as defined in subpart P of this part, shall be identified as such with an asterisk in the ingredients statement. The statement ''*Ingredients not in regular _____'' (the blank shall be filled in with the name of the traditional standardized product) or ''**Ingredients in excess of amounts permitted in regular _____'' (the blank shall be filled in with the name of the traditional standardized product), or both, as appropriate, shall immediately follow the ingredients statement in the same type and size.

Done in Washington, DC, on June 6, 2005.

Barbara J. Masters,

Acting Administrator.

[FR Doc. 05–11493 Filed 6–9–05; 8:45 am]

BILLING CODE 3410–DM–P

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 170 and 171

RIN 3150–AH61

Revision of Fee Schedules; Fee Recovery for FY 2005

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule; correction.

SUMMARY: This document corrects a final rule appearing in the **Federal Register** on May 26, 2005 (70 FR 30526) concerning the licensing, inspection, and annual fees charged to NRC applicants and licensees in compliance with the Omnibus Budget Reconciliation Act of 1990, as amended. This action is necessary to correct typographical and printing errors.

EFFECTIVE DATE: July 25, 2005.

FOR FURTHER INFORMATION CONTACT: Tammy Croote, telephone 301–415–6041; Office of the Chief Financial Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

SUPPLEMENTARY INFORMATION:

1. On page 30531, in the first column, under Response, in the fourteenth line, the word ''commenters?'' is corrected to read ''commenters.''

2. On page 30535, in the second column, under 4. *Charging Fees for Unlicensed Sites in Decommissioning*, in the eleventh line, the word ''licensees?'' is corrected to read ''licensees.''

3. On page 30537, in TABLE III.—REBASELINED ANNUAL FEES FOR FY 2005, the first number under the *FY 2005 Annual Fee* column ''$3,115,000'' is corrected to read ''$3,155,000.''

4. On page 30540, in the second column, in the fourth line of the continued paragraph under Table VIII, the number ''$2,966,000'' is corrected to read ''$2,996,000.'' Also, in the tenth line in the same paragraph, the number ''$3,115,000'' is corrected to read ''$3,155,000.''

PART 170—[AMENDED]

§ 170.31 [Corrected]

■ 5. On page 30547, in § 170.31, in the table entitled SCHEDULE OF MATERIALS FEES, the Category of materials licenses and type of fees column entry for 14.B. ''(insert date 1 year from effective date of final rule)'' is corrected to read ''July 25, 2006.''

PART 171—[AMENDED]

§ 171.15 [Corrected]

■ 6. On page 30548, in § 171.15(b)(1), the number ''$3,115,000'' is corrected to read ''$3,155,000.''

§ 171.16 [Corrected]

■ 7. In § 171.16 (c), the table entitled SCHEDULE OF MATERIALS ANNUAL FEES AND FEES FOR GOVERNMENT AGENCIES LICENSED BY NRC, the Annual Fees column entry for 15. C. On page 30552, the entry ''0N/A[8]'' is corrected to ''[8] N/A.''

Dated in Rockville, Maryland, this 2nd day of June, 2005.

For the Nuclear Regulatory Commission.

Jesse L. Funches,

Chief Financial Officer.

[FR Doc. 05–11495 Filed 6–9–05; 8:45 am]

BILLING CODE 7590–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2005–21092; Directorate Identifier 2005–CE–20–AD; Amendment 39–14118; AD 2005–12–02]

RIN 2120–AA64

Airworthiness Directives; Revo, Incorporated Models Colonial C–2, Lake LA–4, Lake LA–4A, Lake LA–4P, and Lake LA–4–200 Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) to supersede Airworthiness Directive (AD) 98–10–12, which applies to all Revo, Incorporated (REVO) (Type Certificate 1A13 formerly held by Colonial Aircraft Company, Lake Aircraft Corporation, Consolidated Aeronautics, Inc., and Global Amphibians LLC) Models Colonial C–2, Lake LA–4, Lake LA–4A, Lake LA–4P, and Lake LA–4–200 airplanes. AD 98–10–12 currently requires you to ensure adequate clearance between the attachment fitting and the horizontal stabilizer rear beam and between the attachment fitting and the stabilizer skin with inspections, possible replacement, and adjustments as necessary. This new AD is the result of several reports of fatigue cracks found in the horizontal stabilizer attachment fitting (part number 2–2200–21) of Model LA–4–200 airplanes that were in compliance with AD 98–10–12. This includes an airplane accident with a fatality attributed to a fatigue crack in the horizontal stabilizer attachment fitting. Consequently, this AD requires either a dye penetrant inspection of the horizontal stabilizer attachment fitting for any evidence of fretting, cracking, or corrosion (with necessary replacement and modification) or replacement of the fittings depending on the number of operational hours on the fitting. The AD also requires you to repetitively replace the fitting every 850 hours time-in-service (TIS), repetitively inspect (visually) the fittings between replacement times, and report to FAA the results of the initial inspection and any cracks found on repetitive inspections. We are issuing this AD to detect, correct, and prevent future cracks in the horizontal stabilizer attachment fitting, which could result in failure of the horizontal stabilizer attachment fitting. This failure could result in loss of control of the airplane.

DATES: This AD becomes effective on July 8, 2005.

As of July 8, 2005, the Director of the Federal Register approved the incorporation by reference of certain publications listed in the regulation.

We must receive any comments on this AD by August 8, 2005.

ADDRESSES: Use one of the following to submit comments on this AD:

- *DOT Docket Web site:* Go to *http://dms.dot.gov* and follow the instructions for sending your comments electronically.
- *Government-wide rulemaking Web site:* Go to *http://www.regulations.gov* and follow the instructions for sending your comments electronically.
- *Mail:* Docket Management Facility; U.S. Department of Transportation, 400 Seventh Street, SW., Nassif Building, Room PL–401, Washington, DC 20590–001.
- *Fax:* 1–202–493–2251.
- *Hand Delivery:* Room PL–401 on the plaza level of the Nassif Building, 400 Seventh Street, SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

To get the service information identified in this proposed AD, contact Revo, Incorporated, 1396 Grandview Boulevard, Kissimmee, FL 34744.

To view the comments to this AD, go to *http://dms.dot.gov*. The docket number is FAA–2005–21092; Directorate Identifier 2005–CE–20–AD.

FOR FURTHER INFORMATION CONTACT: Cindy Lorenzen, Aerospace Engineer, FAA, Atlanta Aircraft Certification Office, 1895 Phoenix Boulevard, suite 450, Atlanta, Georgia 30349; telephone: (770) 703–6078; facsimile: (770) 703–6097.

SUPPLEMENTARY INFORMATION:

Has FAA taken any action to this point? A report of loss of control on a Revo, Incorporated (REVO) Lake LA–4 series airplane during flight caused us to issue AD 98–10–12, Amendment 39–10524 (63 FR 26964, May 15, 1998). AD 98–10–12 currently requires the following on all REVO (Type Certificate 1A13 formerly held by Colonial Aircraft Company, Lake Aircraft Corporation, Consolidated Aeronautics, Inc., and Global Amphibians LLC) Models Colonial C–2, Lake LA–4, Lake LA–4A, Lake LA–4P, and Lake LA–4–200 airplanes:

- Measuring for a clearance of 5/32 of an inch between the attachment fitting and the horizontal stabilizer rear beam.
- If this minimum measurement is not met, removing the affected horizontal tail half from the airplane and inspecting the attachment fitting for any evidence of fretting, cracking, or corrosion.
- If cracks, fretting, or corrosion are/is present, replacing the attachment fitting with a new fitting, ensuring a clearance of 1/16 of an inch exists between the attachment fitting, and, if needed, trimming the stabilizer skin to provide a positive clearance for the fitting.

What has happened since AD 98–10–12 to initiate this AD action? The FAA has received more reports of fatigue cracks found in the horizontal stabilizer attachment fitting (part number (P/N) 2–2200–21) of REVO Model LA–4–200 airplanes. These airplanes were in compliance with AD 98–10–12. This includes one report of a REVO Model LA–4–200 airplane accident with a fatality attributed to a fatigue crack in the horizontal stabilizer attachment fitting.

The cracks occurred with as little as 942 hours time-in-service (TIS) on the horizontal stabilizer attachment fitting.

What is the potential impact if FAA took no action? Failure of the horizontal stabilizer attachment fitting (P/N 2–2200–21) could result in loss of control of the airplane.

Is there service information that applies to this subject? REVO has issued Service Bulletin B–78, dated April 3, 1998.

What are the provisions of this service information? The service bulletin includes procedures for:

—Removing the fitting and inspecting (both visual and dye penetrant) for cracks, fretting, or corrosion;
—Replacing the attachment fitting with a new fitting;
—Measuring the gap between the attachment fitting and the horizontal

stabilizer skin for proper clearance; and
—Trimming the stabilizer skin to provide proper clearance.

FAA's Determination and Requirements of the AD

What has FAA decided? We have evaluated all pertinent information and identified an unsafe condition that is likely to exist or develop on other products of this same type design.

Since the unsafe condition described previously is likely to exist or develop on other REVO (Type Certificate 1A13 formerly held by Colonial Aircraft Company, Lake Aircraft Corporation, Consolidated Aeronautics, Inc., and Global Amphibians LLC) Models Colonial C–2, Lake LA–4, Lake LA–4A, Lake LA–4P, and Lake LA–4–200 airplanes of the same type design, we are issuing this AD to detect, correct, and prevent future cracks in the horizontal stabilizer attachment fitting (P/N 2–2200–21), which could result in failure of the horizontal stabilizer attachment fitting. This failure could result in loss of control of the airplane.

What does this AD require? This AD supersedes AD 98–10–12 by requiring the following:

- Dye penetrant inspection of the horizontal stabilizer attachment fitting for any evidence of fretting, cracking, or corrosion (with necessary replacement and modification) for those airplanes with less than 825 hours TIS on the fitting;
- Replacement of the fittings for those airplanes with 825 or more hours TIS on the fittings;
- Repetitive replacement of the fitting every 850 hours time-in-service (TIS);
- Repetitive visual inspections of the fitting every 50 hours TIS (or at the next annual inspection) between the fitting replacements; and
- Submittal of a report to FAA on the findings of the initial inspection and report of any cracks found for the repetitive inspections.

In preparing this rule, we contacted type clubs and aircraft operators to get technical information and information on operational and economic impacts. As a result of this contact, we received a report of an additional airplane with a crack in the fitting. This airplane had 942 hours total TIS. Consequently, we adjusted the compliance times in the AD based on this information.

How does the revision to 14 CFR part 39 affect this AD? On July 10, 2002, we published a new version of 14 CFR part 39 (67 FR 47997, July 22, 2002), which governs FAA's AD system. This regulation now includes material that relates to altered products, special flight permits, and alternative methods of compliance. This material previously was included in each individual AD. Since this material is included in 14 CFR part 39, we will not include it in future AD actions.

Comments Invited

Will I have the opportunity to comment before you issue the rule? This AD is a final rule that involves requirements affecting flight safety and was not preceded by notice and an opportunity for public comment; however, we invite you to submit any written relevant data, views, or arguments regarding this AD. Send your comments to an address listed under **ADDRESSES.** Include ''Docket No. FAA–2005–21092; Directorate Identifier 2005–CE–20–AD'' in the subject line of your comments. If you want us to acknowledge receipt of your mailed comments, send us a self-addressed, stamped postcard with the docket number written on it; we will date-stamp your postcard and mail it back to you. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of the rule that might suggest a need to modify it. If a person contacts us through a nonwritten communication, and that contact relates to a substantive part of this AD, we will summarize the contact and place the summary in the docket. We will consider all comments received by the closing date and may amend the AD in light of those comments.

Authority for This Rulemaking

What authority does FAA have for issuing this rulemaking action? Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority.

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701, ''General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this AD.

Regulatory Findings

Will this AD impact various entities? We have determined that this AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect 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.

Will this AD involve a significant rule or regulatory action? For the reasons discussed above, I certify that this AD:

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. 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.

We prepared a summary of the costs to comply with this AD (and other information as included in the Regulatory Evaluation) and placed it in the AD Docket. You may get a copy of this summary by sending a request to us at the address listed under **ADDRESSES.** Include ''AD Docket FAA–2005–21092; Directorate Identifier 2005–CE–20–AD'' in your request.

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

■ Accordingly, under 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. The FAA amends § 39.13 by removing Airworthiness Directive (AD) 98–10–12, Amendment 39–10524 (63 FR 26964, May 15, 1998), and by adding a new AD to read as follows:

2005–12–02 Revo, Incorporated (Type Certificate 1A13 formerly held by Colonial Aircraft Company, Lake Aircraft Corporation, Consolidated Aeronautics, Inc., and Global Amphibians LLC): Amendment 39–14118; Docket No. FAA–2005–21092; Directorate Identifier 2005–CE–20–AD.

When Does This AD Become Effective?

(a) This AD becomes effective on July 8, 2005.

Are Any Other ADs Affected By This Action?

(b) Yes. This AD supersedes AD 98–10–12; Amendment 39–10524.

What Airplanes Are Affected by This AD?

(c) This AD affects Models Colonial C–2, Lake LA–4, Lake LA–4A, Lake LA–4P, and Lake LA–4–200, all serial numbers, that are certificated in any category.

What is the Unsafe Condition Presented in This AD?

(d) This AD is the result of several reports of fatigue cracks found in the horizontal stabilizer attachment fitting (part number (P/N) 2–2200–21) of Model LA–4–200 airplanes and one report of a Model LA–4–200 airplane accident with a fatality attributed to a fatigue crack in the horizontal stabilizer attachment fitting. We are issuing this AD to detect, correct, and prevent future cracks in the horizontal stabilizer attachment fitting (P/N 2–2200–21), which could result in failure of the horizontal stabilizer attachment fitting. This failure could result in loss of control of the airplane.

What Must I Do To Address This Problem?

(e) To address this problem, you must do the following:

Actions	Compliance	Procedures
(1) *For airplanes with 825 hours time-in-service (TIS) or more on any horizontal stabilizer attachment fitting as of July 8, 2005 (the effective date of this AD):* (i) Replace the horizontal stabilizer attachment fitting (part number (P/N) 2–2200–21). (ii) If necessary, trim the horizontal stabilizer rear beam doubler flange to provide positive clearance to the fitting.	Within the next 25 hours TIS after July 8, 2005 (the effective date of this AD) Repetitively replace any horizontal stabilizer attachment fitting (P/N 2–2200–21) thereafter following paragraph (e)(3) of this AD.	Follow Revo, Inc. Service Bulletin B–78, dated April 3, 1998, paragraphs 2 and 3 of the INSPECTION and REPAIR section and the APPENDIX.
(2) *For airplanes with less than 825 hours TIS on any horizontal stabilizer attachment fitting as of July 8, 2005 (the effective date of this AD):* (i) Remove the horizontal stabilizer attachment fitting (P/N 2–2200–21) from the airplane and inspect for cracks (using dye penetrant), fretting, or corrosion. To take ''already done'' credit for this, you must have removed the fitting from the airplane when the inspection was done. (ii) Replace any horizontal stabilizer attachment fitting if you find any cracks, fretting, or corrosion.	Inspect within the next 25 hours TIS after July 8, 2005 (the effective date of this AD), unless already done. If cracks, fretting, or corrosion is found, replace before further flight after the inspection.	Follow Revo, Inc. Service Bulletin B–78, dated April 3, 1998, INSPECTION and REPAIR section and the APPENDIX.
(3) *For all airplanes:* Repetitively replace the horizontal stabilizer attachment fittings upon accumulating 850 hours TIS on the fittings.	Every 850 hours TIS	Follow Revo, Inc. Service Bulletin B–78, dated April 3, 1998, paragraphs 2 and 3 of the INSPECTION and REPAIR section and the APPENDIX.
(4) *For all airplanes:* Measure the gap between the horizontal skin and the horizontal stabilizer attachment fitting (P/N 2–2200–21). If gap is less than 1/16-inch, trim the skin to provide at least 1/16-inch gap.	Before further flight after any replacement of the fitting required by paragraphs (e)(1), (e)(2), and (e)(3) of this AD.	Follow Revo, Inc. Service Bulletin B–78, dated April 3, 1998.
(5) *For all airplanes:* Repetitively inspect (visual) the horizontal stabilizer attachedment fitting using the following procedures. (i) Move the elevator as required to see the fitting, ensuring that the aft face of the fitting is visible. (ii) Clean the fitting. Pay special attention to the radius edges of the fitting just outboard of the fitting ear. (iii) Visually inspect the fitting for cracks using a flashlight (a small magnifying glass or borescope is recommended). Pay special attention again to the radius edges just outboard of the fitting ear. Also, inspect as far forward on the edge that is possible because some cracks progress along the forward face of the fitting that is mostly hidden by the horizontal stabilizer rear beam. (iv) Reference the sketch on page 1 of the Service Bulletin B–78 to see where the crack is likely to begin. (v) Replace the fitting prior to further flight if cracks are found during any of these inspections.	Repetitively inspect at whichever of the following that occurs first (first repetitive starts after the initial inspection or replacement): • 50 hours TIS; or • the next annual inspection Replace the fitting prior to further flight after any inspection where cracks are found.	Follow the procedures presented in the Actions column of this paragraph, including the sketch on page 1 of the Service Bulletin B–78.

Actions	Compliance	Procedures
(6) *For all airplanes:* Report to FAA the results of the initial inspection required by paragraph (e)(2) of this AD even if no damage is found, and report the results of the repetitive inspections required by paragraph (e)(2) of this AD only if cracks are found. The Office of Management and Budget (OMB) approved the information collection requirements contained in this regulation under the provisions of Paperwork Reduction Act of 1980 (44 U.S.C. 3501 and those following sections) and assigned OMB Control Number 2120–0056.	Within 10 days after the inspection required by paragraph (e)(2) or (e)(5) of this AD or within 10 days after July 8, 2005 (the effective date of this AD), whichever occurs later.	Send the form (Figure 1 of this AD) to FAA, Atlanta ACO, 1895 Phoenix Boulevard, suite 450, Atlanta, Georgia 30349; telephone: (770) 703–6078; facsimile: (770) 703–6097.
(7) *For all airplanes:* Do not install used serviceable fittings, unless you know the number of accumulated hours TIS and have inspected following the requirements of paragraph (e)(2) of this AD.	As of July 8, 2005 (the effective date of this AD).	Not Applicable.

BILLING CODE 4910–13–P

*AD **-**-** INSPECTION REPORT*	
1. Inspection Performed By:	*2. Telephone:*
3. Aircraft Model:	*4. Aircraft Serial Number:*
5. Date of AD Inspection:	*6. Total hours time-in-service (TIS) on the fitting:*
7. Cracks found? ☐ *Yes* ☐ *No* ☐ *Left fitting* ☐ *Right fitting*	*8. Length of Crack(s):* *Left fitting:* *Right fitting*
9. Fretting found? ☐ *Yes* ☐ *No* ☐ *Left fitting* ☐ *Right fitting*	*10. Corrosion found?* ☐ *Yes* ☐ *No* ☐ *Left fitting* ☐ *Right fitting*
Send to: Federal Aviation Administration Atlanta Aircraft Certification Office 1895 Phoenix Boulevard, Suite 450 Atlanta, Georgia 30349 Telephone: (770) 703-6078 Facsimile: (770) 703-6097	

Figure 1.

BILLING CODE 4910–13–C

May I Request an Alternative Method of Compliance?

(f) You may request a different method of compliance or a different compliance time for this AD by following the procedures in 14 CFR 39.19. Unless FAA authorizes otherwise, send your request to your principal inspector. The principal inspector may add comments and will send your request to the Manager, Atlanta Aircraft Certification Office (ACO), FAA. For information on any already approved alternative methods of compliance, contact Cindy Lorenzen, Aerospace Engineer, FAA, Atlanta ACO, 1895 Phoenix Boulevard, suite 450, Atlanta, Georgia 30349; telephone: (770) 703–6078; facsimile: (770) 703–6097.

May I Obtain a Special Flight Permit for the Initial Inspection or Replacement Requirement of This AD?

(g) Yes. Special flight permits are allowed for this AD with these limitations:

(1) Vne reduced to 121 m.p.h. (105 knots); and

(2) No flight into known turbulence.

Does This AD Incorporate Any Material by Reference?

(h) You must do the actions required by this AD following the instructions in Revo, Inc. Service Bulletin B–78, dated April 3, 1998. The Director of the Federal Register approved the incorporation by reference of this service bulletin in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. To get a copy of this service information, contact Revo, Incorporated, 1396 Grandview Boulevard, Kissimmee, FL 34744. To review copies of this service information, go to the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html* or call (202) 741–6030. To view the AD docket, go to the Docket Management Facility; U.S. Department of Transportation, 400 Seventh Street, S.W., Nassif Building, Room PL–401, Washington, DC 20590–001 or on the Internet at *http://dms.dot.gov.* The docket number is FAA–2005–21092; Directorate Identifier 2005–CE–20–AD.

Issued in Kansas City, Missouri, on June 2, 2005.

Kim Smith,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 05–11361 Filed 6–9–05; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF COMMERCE

International Trade Administration

15 CFR part 335 and 340

Docket Number: 001229368-5150-03

RIN: 0625-AA58

Imports of Certain Worsted Wool Fabric: Implementation of Tariff Rate Quota Established Under Title V of the Trade and Development Act of 2000

AGENCY: Department of Commerce, International Trade Administration.

ACTION: Final rule; withdrawal.

SUMMARY: The Department of Commerce (''Commerce'') is withdrawing its final rule entitled ''Imports of Certain Worsted Wool Fabric: Implementation of Tariff Rate Quota Established Under Title V of the Trade and Development Act of 2000'' published on May 12, 2005 (70 FR 24941). That rule finalized tariff rate quotas (TRQ) for a limited quantity of worsted wool fabrics pursuant to Title V of the Trade and Development Act of 2000 (''the Act'') as amended by the Trade Act of 2002. The rule is being withdrawn due to an incorrect effective date.

DATES: The final rule published on May 12, 2005 at 70 FR 24941 is withdrawn as of June 10, 2005.

FOR FURTHER INFORMATION CONTACT: Sergio Botero, Office of Textiles and Apparel, U.S. Department of Commerce, (202) 482-4058.

SUPPLEMENTARY INFORMATION: The Department of Commerce (''Commerce'') is withdrawing its final rule published on May 12, 2005 at 70 FR 24941. That rule finalized tariff rate quotas (TRQ) for a limited quantity of worsted wool fabrics pursuant to Title V of the Trade and Development Act of 2000 (''the Act'') as amended by the Trade Act of 2002. The rule is being withdrawn because the effective date of the rule is incorrect. The effective date for the final rule was incorrectly established for June 13, 2005.

Commerce currently has open for comment a related interim final rule that implements amendments made by the Miscellaneous Trade Act of 2004 (70 FR 25774). Comments may be submitted until 5:00 p.m. on July 15, 2005. Please see the interim final rule for background information and instructions for submitting comments.

Classification: It has been determined that this notice is not significant for purposes of E.O. 12866.

The Department finds good cause to waive prior notice and an opportunity for public comment required by the Administrative Procedure Act because it is unnecessary and contrary to the public interest. Prior notice and opportunity for public comment is unnecessary because this rule will not have a substantive impact on the affected industry. The provisions implemented by the May 12, 2005 rule are not currently in effect and have not impacted the regulated industry. The withdrawal of the May 12, 2005 rule will, therefore, not substantively change the requirements currently imposed on the regulated industry. It would be contrary to the public interest to allow for prior notice and an opportunity for public comment because the published effective date of the May 12, 2005 rule conflicts with an interim final rule that implemented recently enacted statutory amendments. Consequently, if the May 12, 2005 rule is allowed to go into effect, it would create confusion in the industry. Therefore, it is unnecessary and contrary to the public interest to provide prior notice and an opportunity for public comment.

The Department finds that the 30-day in effectiveness is inapplicable because this rule is not a substantive rule. The provisions implemented by the May 12, 2005 rule are not currently in effect and its withdrawal will not substantively change the requirements currently imposed on the regulated industry.

Because notice and opportunity for comment are not required pursuant to 5 USC 553 or any other law, the analytical requirements of the Regulatory Flexibility Act (5 USC 601 et seq.) are inapplicable. Therefore, a regulatory flexibility analysis is not required and has not been prepared.

Dated: June 7, 2005.

Joseph A. Spetrini

Acting Assistant Secretary for Import Administration.

[FR Doc. 05–11595 Filed 6–9–05; 8:45 am]

BILLING CODE 3510–DS–S

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Part 4

[Docket No. RM05–18–000; Order No. 655]

Modification of Hydropower Procedural Regulations, Including the Deletion of Certain Outdated or Non-Essential Regulations

May 27, 2005.

AGENCY: Federal Energy Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Federal Energy Regulatory Commission (Commission) is amending its regulations concerning applications for preliminary permits to eliminate certain outdated requirements and reduce unnecessary burdens on persons subject to the Commission's regulations. These modifications are the result of a review begun by the Commission's FERC Information Assessment Team (FIAT) to identify all of the Commission's current information collections to evaluate their original purposes and current uses, and to propose ways to reduce the burden on industry through the elimination, reduction, streamlining or reformatting of current collections. The Commission is amending its regulations to eliminate 18 CFR 4.81(d)(3) to remove the requirements for identifying a market for power and related power system information in the application for a preliminary permit. The Commission expects that these minor modifications of its regulations will not have a significant impact on preliminary permit proceedings. Because these changes relate only to the Commission's procedures and relieve unnecessary regulatory burdens, notice and comment on the changes is not required.

EFFECTIVE DATE: July 11, 2005.

FOR FURTHER INFORMATION CONTACT:

William O. Blome (Legal Information), Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, (202) 502–8462.

Thomas E. DeWitt (Technical Information), Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, (202) 502–6070.

SUPPLEMENTARY INFORMATION:

Before Commissioners: Pat Wood, III, Chairman; Nora Mead Brownell, Joseph T. Kelliher, and Suedeen G. Kelly.

I. Introduction

1. The Federal Energy Regulatory Commission (Commission) has reviewed its hydropower procedural regulations to determine whether they contain any outdated requirements or impose any unnecessary burdens on persons subject to the Commission's jurisdiction. This review was begun by the FERC Information Assessment Team (FIAT), which was directed by the Chairman to assess the Commission's information needs. Goal 2 of the tasks identified by the team to meet this mission included identifying all of the Commission's current information collections, through forms and filing requirements, and evaluating their original purposes and current uses, and proposing ways to reduce the reporting burden on industry through elimination, reduction, streamlining or reformatting of current collections.

2. In this final rule, the Commission is amending its regulations to eliminate 18 CFR 4.81(d) (3), in order to remove the requirement that the applicant for a preliminary permit must identify a market for the power that it proposes to generate and provide related power system information at the preliminary permit stage of a hydropower license application. At the preliminary permit stage, the applicant is not required to develop a proposed project in detail, so this information is unnecessary.

3. The Commission expects these regulations will reduce the amount of information the Commission requires applicants to file, and that these modifications will not have a significant impact on preliminary permit proceedings. Because these changes relate only to the Commission's procedures and relieve unnecessary regulatory burdens, notice and comment on the changes is not required, and the changes are effective July 11, 2005.

4. The Commission's regulations provide a range of alternatives for development of a hydropower project. A prospective developer may, *inter alia*, apply to the Commission for a preliminary permit under Section 4(f) of the Federal Power Act.[1] These permits allow a specified term, no more than three years, for the prospective developer to perform investigations and studies to support a license application and to determine the economic, engineering and environmental feasibility of developing a hydropower project at a specific site. The permit preserves the exclusive right to file, during the specified term, an application for either a license or an exemption from licensing for the proposed project. Thus, the permittee may conduct needed studies to determine the feasibility of the project without fear of someone else filing a development application for the site. A preliminary permit is not required to develop a project; a developer may choose to file directly for either a license or an exemption from licensing. Preliminary permits are not transferable.

II. Discussion

5. The Commission regulates non-Federal hydropower development under Part I of the Federal Power Act[2] (FPA). The Commission issues licenses for terms up to 50 years for ''projects best adapted to a comprehensive plan'' for improving a waterway for beneficial public purposes. Pursuant to Section 4(f) of the FPA, the Commission is authorized to issue preliminary permits, for the purpose of enabling prospective license applicants to secure the information necessary to support an application for license. Preliminary permits, issued for three years, reserve the right to file a development application at a specific site,[3] but do not authorize construction of any hydropower facilities or other land-disturbing activities.[4]

6. The purpose of obtaining a preliminary permit, as noted above, is to maintain a priority status for an application for a license while the prospective applicant conducts site examinations and surveys to prepare maps, plans, specifications and estimates. This period of time also provides the applicant with the opportunity to conduct engineering, economic and environmental feasibility studies, and to make financial arrangements for the construction of any project. During the term of the permit, the Commission will accept no other application for a preliminary permit or application for license or exemption submitted by another person for the same site.

7. The Commission is eliminating 18 CFR 4.81(d) (3), thus eliminating the need for preliminary permit applicants to identify the market for the power that they propose to generate and to provide certain related power system information. At the time of a preliminary permit application, the project proposal is necessarily incomplete and this information is not needed to understand the project at this stage. The Commission is also incorporating 18 CFR 4.81(d) (1) and (2), concerning study costs and financing sources, into 18 CFR 4.81(c), which requires the applicant to describe studies conducted or to be conducted in connection with the preparation of a development application for the proposed project. These rules benefit applicants for preliminary permits by simplifying and expediting the preliminary permit process.

III. Information Collection Statement

8. Office of Management and Budget (OMB) regulations require OMB to approve certain information collection requirements imposed by agency rule.[5] Comments are solicited on the Commission's need for this information,

[1] 16 U.S.C. 797(f) (2000).

[2] 16 U.S.C. 791a, *et seq.* (2000).

[3] See FPA Section 5, 16 U.S.C. 798.

[4] See, *e.g.*, Greenfields Irrigation District, 111 FERC ¶ 62,039 (2005).

[5] 5 CFR 1320.11.

whether it will have practical utility, the accuracy of burden estimates, ways to enhance the quality, utility and clarity of the information to be collected, and any suggested methods for minimizing respondents' burden, including the use of automated information techniques.

IV. Estimated Annual Burden

9. The current reporting burden for this information collection is as follows:

Data collection	Number of respondents	Number of hours	Number of responses	Total annual hours
FERC–512	50	73	1	3,650

The Commission estimates that preliminary permit applications filed pursuant to the new rule would require approximately 15 percent less time to prepare. Using an assumed cost of $52 per hour, the total savings would be $572 per application or $28,000 saved for a year in which 50 applications are prepared and filed.

Title: Application for Preliminary Permit (FERC–512).

Action: Change to an Existing Collection.

OMB Control No.: 1902–0073.

Respondents: Businesses or other for-profit and not-for-profit institutions.

Frequency of Responses: On occasion.

Necessity of Information: The proposed regulations will revise the reporting requirements for a preliminary permit application to streamline the requirements and reduce the burden on the applicant. The information filed with the Commission preserves a priority to file by a prospective developer of a hydropower project. These permits allow a specified time for the developer to conduct investigations necessary to support a license application and to determine the economic, engineering and environmental feasibility of developing a hydropower project at a certain site. The preliminary permit is not required to develop a project. Therefore, the developer may file directly for either a license or an exemption from licensing. The Commission offers preliminary permits as part of its efforts to simplify and expedite the hydropower licensing process. This final rule will take those efforts one step further.

Internal Review: The Commission has reviewed the proposed amendments to its regulations to remove the requirement that an applicant for a preliminary permit must identify a market for the power that it proposes to generate and provide related power system information at the preliminary permit stage of a hydropower license application. At the preliminary permit application stage, it is not necessary for the applicant to provide information regarding a market for the project's power and related matters. This amendment to the Commission's regulations conforms to the Commission's plan for efficient information collection, communication, and management within the hydropower industry. The Commission has assured itself, by means of internal review, that the new rule will reduce the burden estimates associated with preliminary permit applications.

10. Interested persons may obtain information on the information requirements by contacting the following: The Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426 [Attention: Michael Miller, Office of the Executive Director, Phone (202) 502–8415, fax: (202) 273–0873, e-mail: *michael.miller@ferc.gov.*]

11. Please send your comments concerning the collection of information(s) and the associated burden estimate(s) to the contact listed above and to the Office of Management and Budget, Office of Information and Regulatory Affairs, Washington, DC 20503, [Attention: Desk Officer for the Federal Energy Regulatory Commission, phone: (202) 395–4650, fax: (202) 395–7285].

V. Environmental Analysis

12. The Commission is required to prepare an Environmental Assessment or an Environmental Impact Statement for any action that may have a significant adverse effect on the human environment.[6] The Commission has categorically excluded certain actions from these requirements as not having a significant effect on the human environment.[7] The action taken here falls within the categorical exclusions in the Commission's regulations for rules that involve information gathering, analysis, and dissemination.[8] This proposed rule, if finalized, is procedural in nature and therefore falls under this exception. Therefore, an environmental assessment is unnecessary and one has not been prepared for this rulemaking.

[6] Order No. 486, *Regulations Implementing the National Environmental Policy Act*, Order No. 486, 52 FR 47897 (Dec. 17, 1987), FERC Stats. & Regs. ¶ 30,783 (1987).

[7] 18 CFR 380.4(a) (2) (ii).

[8] 18 CFR 380.4(a) (5).

VI. Regulatory Flexibility Act Certification

13. The Regulatory Flexibility Act of 1980 (RFA)[9] requires a description and analysis of final rules that will have significant economic impact on a substantial number of small entities.[10] The Commission is not required to make such analyses if a rule would not have such an effect.

14. The Commission has concluded that the amendments to its regulations would not have such an impact on small entities. These regulations are intended to benefit all entities regardless of size by reducing the burden of information collection while preparing an application for a preliminary permit. The adoption of these amendments to the regulations will reduce the amount of information that must be filed with the Commission and will be of greater benefit to small entities who have limited resources for conducting investigations and preparing a licensing application if they so choose. Therefore, the Commission certifies that this rule will not have a significant economic impact on a substantial number of small entities.

VIII. Document Availability

15. In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and print the contents of this document via the Internet through FERC's Home Page *(http://www.ferc.gov)* and in FERC's Public Reference Room during normal business hours (8:30 a.m. to 5 p.m. eastern time) at 888 First Street, NE., Room 2A, Washington, DC 20426.

[9] 5 U.S.C. 601–612 (2000).

[10] The RFA definition of ''small entity'' refers to the definition provided in the Small Business Act, which defines a ''small business concern'' as a business which is independently owned and operated and which is not dominant in its field of operation. 15 U.S.C. 632 (2000). The Small Business Size standards component of the North American Industry Classification System defines a small electric utility as one that, including its affiliates, is primarily engaged in the generation, transmission, and/or distribution of electric energy for sale and whose total electric output for the preceding fiscal years did not exceed four million megawatthours. 13 CFR 121.201 (Section 22, Utilities, NAICS) (2004).

16. From FERC's Home Page on the Internet, this information is available in the Commission's document management system, eLibrary, using the eLibrary link. The full text of this document is available on eLibrary in PDF and Microsoft Word format for viewing, printing and downloading. To access this document in eLibrary, type the docket number of this document, excluding the last three digits, in the docket number field.

17. User assistance is available for eLibrary and the FERC's Web site during normal business hours. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or calling toll-free at (866) 208–3676. For TTY, contact (202) 502–8659, or the Public Reference Room at (202) 502–8371, TTY (202) 502–8659, (e-mail at *public.referenceroom@ferc.gov*).

IX. Effective Date and Congressional Notification

18. This Final Rule will take effect July 11, 2005. The Commission has determined, with the concurrence of the Administrator of the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), that this rule is not a major rule within the meaning of Section 251 of the Small Business Regulatory Enforcement Fairness Act of 1996.[11] The Commission will submit the Final Rule to both houses of Congress and to the General Accountability Office.[12]

19. The Administrative Procedure Act (APA)[13] requires rulemakings to be published in the **Federal Register**. It also requires that an opportunity for comment be provided when the agency promulgates regulations. However, notice and comment are not required by the APA when the agency for good cause finds that notice and public comments thereon are impracticable, unnecessary, or contrary to the public interest.[14] The Commission finds that notice and comment are unnecessary to this rulemaking. As explained above, we are merely clarifying the scope of our regulations concerning applications for preliminary permits. This action should benefit the public by reducing the need to provide more information than is necessary for the Commission to evaluate preliminary permit applications. This clarification will result in a reduction of the filing requirements and will decrease the reporting burden on persons planning to develop hydroelectric power projects. Accordingly, this rule is effective July 11, 2005.

[11] *See* 5 U.S.C. 804(2) (2000).

[12] *See* 5 U.S.C. 801(a)(1)(A) (2000).

[13] 5 U.S.C. 551–559 (2000).

[14] 5 U.S.C. 553(b)(3)(B) (2000).

List of Subjects in 18 CFR Part 4

Hydropower, Reporting and recordkeeping requirements.

By the Commission.

Linda Mitry,

Deputy Secretary.

■ In consideration of the foregoing, the Commission amends part 4, Chapter 1, Title 18, Code of Federal Regulations, as follows:

PART 4—LICENSES, PERMITS, EXEMPTIONS, AND DETERMINATIONS OF PROJECT COSTS

■ 1. The authority citation for part 4 continues to read as follows:

Authority: 16 U.S.C. 791a–825r, 2601–2645; 42 U.S.C. 7101–7352.

§ 4.81 [Amended]

■ 2. In § 4.81,

■ a. Remove paragraph (d)(3);

■ b. Paragraphs (d) introductory text, (d)(1) and (d)(2) are redesignated as paragraphs (c)(4) introductory text, (c)(4)(i) and (c)(4)(ii);

■ c. In the redesignated paragraph (c)(4) introductory text, the words ''Exhibit 3'' are removed and the words ''Exhibit 2'' are inserted in their place;

■ d. Paragraph (e) is redesignated as paragraph (d);

■ e. In redesignated paragraph (d), the words ''Exhibit 4'' are removed and the words ''Exhibit 3'' are inserted in their place.

[FR Doc. 05–11551 Filed 6–9–05; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[CGD05–05–052]

RIN 1625–AA08

Special Local Regulation for Marine Events; Nanticoke River, Sharptown, MD

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing temporary special local regulations during the ''Bo Bowman Memorial—Sharptown Regatta'', a marine event to be held on the waters of the Nanticoke River near Sharptown, Maryland. These special local regulations are necessary to provide for the safety of life on navigable waters during the event. This action is intended to restrict vessel traffic in the Nanticoke River during the event.

DATES: This rule is effective from 9:30 a.m. on July 2, to 6:30 p.m. on July 4, 2005.

ADDRESSES: Comments and material received from the public, as well as documents indicated in this preamble as being available in the docket, are part of docket CGD05–05–052 and are available for inspection or copying at Commander (oax), Fifth Coast Guard District, 431 Crawford Street, Portsmouth, Virginia 23704–5004, between 9 a.m. and 2 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Dennis Sens, Project Manager, Auxiliary and Recreational Boating Safety Branch, at (757) 398–6204.

SUPPLEMENTARY INFORMATION:

Regulatory Information

We did not publish a notice of proposed rulemaking (NPRM) for this regulation. Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing an NPRM. Publishing an NPRM would be impracticable and contrary to public interest. The event will take place on July 2, 3, and 4, 2005. Immediate action is needed to protect the safety of life at sea from the danger posed by high-speed powerboats.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date would be contrary to the public interest, since immediate action is needed to ensure the safety of the event participants, spectator craft and other vessels transiting the event area. However advance notifications will be made to affected waterway users via marine information broadcasts and area newspapers.

Background and Purpose

On July 2, 3 and 4, 2005, the Carolina Virginia Racing Association will sponsor the ''Bo Bowman Memorial—Sharptown Regatta'', on the waters of the Nanticoke River at Sharptown, Maryland. The event will consist of approximately 100 hydroplanes and runabout conducting high-speed competitive races on the waters of the Nanticoke River between the Maryland S.R. 313 Highway Bridge and Nanticoke River Light 43 (LLN 24175). A fleet of spectator vessels normally gathers nearby to view the competition. Due to the need for vessel control before, during and after the event, vessel traffic

will be temporarily restricted to provide for the safety of participants, spectators and transiting vessels.

Discussion of Rule

The Coast Guard is establishing temporary special local regulations on specified waters of the Nanticoke River near Sharptown, Maryland. The regulated area includes the waters of the Nanticoke River between the Maryland S.R. 313 Highway Bridge and Nanticoke River Light 43 (LLN 24175). The temporary special local regulations will be enforced from 9:30 a.m. to 6:30 p.m. on July 2, 3, and 4, 2005, and will restrict general navigation in the regulated area during the power boat race. Except for persons or vessels authorized by the Coast Guard Patrol Commander, no person or vessel may enter or remain in the regulated area during the enforcement period. The Patrol Commander may allow non-participating vessels to transit the regulated area between races, when it is safe to do so. This regulated area is needed to control vessel traffic before, during and after the event to enhance the safety of participants, spectators and transiting vessels.

Regulatory Evaluation

This rule is not a ''significant regulatory action'' under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order. It is not ''significant'' under the regulatory policies and procedures of the Department of Homeland Security (DHS).

We expect the economic impact of this rule to be so minimal that a full Regulatory Evaluation under the regulatory policies and procedures of DHS is unnecessary. Although this regulation will prevent traffic from transiting a portion of the Nanticoke River during the event, the effect of this regulation will not be significant due to the limited duration that the regulated area will be in effect and the extensive advance notifications that will be made to the maritime community via the Local Notice to Mariners, marine information broadcasts, and area newspapers, so mariners can adjust their plans accordingly. Additionally, the regulated area has been narrowly tailored to impose the least impact on general navigation yet provide the level of safety deemed necessary. Vessel traffic may transit the regulated area between heats, when the Coast Guard Patrol Commander deems it is safe to do so.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered whether this rule would have a significant economic impact on a substantial number of small entities. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities. This rule would affect the following entities, some of which might be small entities: The owners or operators of vessels intending to transit or anchor in a portion of the Nanticoke River during the event.

This rule would not have a significant economic impact on a substantial number of small entities for the following reasons. This rule would be in effect for only a limited period. Vessel traffic may transit the regulated area between heats, when the Coast Guard Patrol Commander deems it is safe to do so. Before the enforcement period, we will issue maritime advisories so mariners can adjust their plans accordingly.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this rule would have a significant economic impact on it, please submit a comment (*see* **ADDRESSES**) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104–121), we want to assist small entities in understanding the rule so that they could better evaluate its effects on them and participate in the rulemaking process. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the address listed under **ADDRESSES.** The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247).

Collection of Information

This rule calls for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this rule under that Order and have determined that it does not have implications for federalism.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

Taking of Private Property

This rule will not effect a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

Civil Justice Reform

This rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

Protection of Children

We have analyzed this rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and does not create an environmental risk to health or risk to safety that may disproportionately affect children.

Indian Tribal Governments

This rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

Energy Effects

We have analyzed this rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a ''significant energy action'' under that order because it is not a ''significant regulatory action'' under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The Administrator of the Office of Information and Regulatory Affairs has not designated it as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

Technical Standards

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the Office of Management and Budget, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (*e.g.*, specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

This rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

Environment

We have analyzed this rule under Commandant Instruction M16475.lD, which guides the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA)(42 U.S.C. 4321–4370f), and have concluded that there are no factors in this case that would limit the use of a categorical exclusion under section 2.B.2 of the Instruction. Therefore, this rule is categorically excluded, under figure 2–1, paragraph (34)(h), of the Instruction, from further environmental documentation. Special local regulations issued in conjunction with a regatta or marine parade permit are specifically excluded from further analysis and documentation under that section.

List of Subjects in 33 CFR Part 100

Marine safety, Navigation (water), Reporting and recordkeeping requirements, Waterways.

■ For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 100 as follows:

PART 100—SAFETY OF LIFE ON NAVIGABLE WATERS

■ 1. The authority citation for part 100 continues to read as follows:

Authority: 33 U.S.C. 1233; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add temporary § 100.35–T05–052 to read as follows:

§ 100.35–T05–052, Nanticoke River, Sharptown, MD.

(a) *Definitions.* (1) *Coast Guard Patrol Commander* means a commissioned, warrant, or petty officer of the Coast Guard who has been designated by the Commander, Coast Guard Sector Baltimore.

(2) *Official Patrol* means any vessel assigned or approved by Commander, Coast Guard Sector Baltimore with a commissioned, warrant, or petty officer on board and displaying a Coast Guard ensign.

(3) *Participant* includes all vessels participating in the Bo Bowman Memorial—Sharptown Regatta under the auspices of the Marine Event Permit issued to the event sponsor and approved by Commander, Coast Guard Sector Baltimore.

(b) *Regulated area* includes all waters of the Nanticoke River, near Sharptown, Maryland, between Maryland S.R. 313 Highway Bridge and Nanticoke River Light 43 (LLN 24175), bounded by a line drawn between the following points: southeasterly from latitude 38°32′46″ N, longitude 075°43′14″ W; to latitude 38°32′42″ N, longitude 075°43′09″ W; thence northeasterly to latitude 38°33′04″ N, longitude 075°42′39″ W; thence northwesterly to latitude 38°33′09″ N, longitude 075°42′44″ W; thence southwesterly to latitude 38°32′46″ N, longitude 075°43′14″ W. All coordinates reference Datum NAD 1983.

(c) *Special local regulations.* (1) Except for event participants and persons or vessels authorized by the Coast Guard Patrol Commander, no person or vessel may enter or remain in the regulated area.

(2) The operator of any vessel in the regulated area must:

(i) Stop the vessel immediately when directed to do so by any Official Patrol.

(ii) Proceed as directed by any Official Patrol.

(iii) Unless otherwise directed by the Official Patrol, operate at a minimum wake speed not to exceed six (6) knots.

(c) *Effective period.* This section will be effective from 9:30 a.m. on July 2, to 6:30 p.m. on July 4, 2005.

(d) *Enforcement period.* It is expected that this section will be enforced from 9:30 a.m. to 6:30 p.m. on July 2, 3 and 4, 2005.

Dated: June 1, 2005.

Sally Brice-O'Hara,

Rear Admiral, U.S. Coast Guard, Commander, Fifth Coast Guard District.

[FR Doc. 05–11490 Filed 6–9–05; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[CGD05–05–051]

RIN 1625–AA08

Special Local Regulation for Marine Events; Maryland Swim for Life, Chester River, Chestertown, MD

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing temporary special local regulations for the ''Maryland Swim for Life'', an annual marine event to be held on the waters of the Chester River near Chestertown, Maryland on June 18, 2005. These special local regulations are necessary to provide for the safety of life on navigable waters during the event. This action is intended to restrict vessel traffic in portions of the Chester River during the event.

DATES: This rule is effective from 6:30 a.m. to 1:30 p.m. on June 18, 2005.

ADDRESSES: Comments and material received from the public, as well as documents indicated in this preamble as being available in the docket, are part of docket CGD05–05–051 and are available for inspection or copying at Commander (oax), Fifth Coast Guard District, 431 Crawford Street, Portsmouth, Virginia 23704–5004, between 9 a.m. and 2 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Dennis Sens, Project Manager, Auxiliary and Recreational Boating Safety Branch, at (757) 398–6204.

SUPPLEMENTARY INFORMATION:

Regulatory Information

We did not publish a notice of proposed rulemaking (NPRM) for this regulation. Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing an NPRM. Publishing an NPRM would be impracticable and contrary to public interest. The event will take place on June 18, 2005. Immediate action is needed to protect the safety of life at sea from the danger posed by transiting vessels.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date would be contrary to the public interest, since immediate action is needed to ensure the safety of the event participants, support craft and other vessels transiting the event area. However, advance notifications will be made to affected waterway users via marine information broadcasts and area newspapers.

Background and Purpose

On June 18, 2005, the Maryland Swim for Life Association will sponsor the ''Maryland Swim for Life'', an open water swimming competition held on the waters of the Chester River, near Chestertown, Maryland. Approximately 100 swimmers start from Rolph's Wharf and swim upriver 2.5 miles then swim down river returning back to Rolph's Wharf. A fleet of approximately 20 support vessels accompanies the swimmers. To provide for the safety of participants and support vessels, the Coast Guard will temporarily restrict vessel traffic in the event area during the swim.

Discussion of Rule

The Coast Guard is establishing temporary special local regulations on specified waters of the Chester River, near Chestertown, Maryland. The regulated area includes all waters of the Chester River between Rolph's Wharf and the Maryland S.R. 213 Highway Bridge. The temporary special local regulations will be enforced from 6:30 a.m. to 1:30 p.m. on June 18, 2005, and will restrict general navigation in the regulated area during the swimming event. Except for persons or vessels authorized by the Coast Guard Patrol Commander, no person or vessel may enter or remain in the regulated area during the effective period. The regulated area is needed to control vessel traffic during the event to enhance the safety of participants and transiting vessels.

Regulatory Evaluation

This rule is not a ''significant regulatory action'' under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order. It is not ''significant'' under the regulatory policies and procedures of the Department of Homeland Security (DHS).

We expect the economic impact of this rule to be so minimal that a full Regulatory Evaluation under the regulatory policies and procedures of DHS is unnecessary. Although this regulation will prevent traffic from transiting a portion of the Chester River during the event, the effect of this regulation will not be significant due to the limited duration that the regulated area will be in effect and the extensive advance notifications that will be made to the maritime community via the Local Notice to Mariners, marine information broadcasts, and area newspapers, so mariners can adjust their plans accordingly.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered whether this rule would have a significant economic impact on a substantial number of small entities. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities. This rule would affect the following entities, some of which might be small entities: The owners or operators of vessels intending to transit or anchor in a portion of the Chester River during the event.

This rule would not have a significant economic impact on a substantial number of small entities for the following reasons. This rule would be in effect for only a limited period. Before the enforcement period, we will issue maritime advisories so mariners can adjust their plans accordingly.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this rule would have a significant economic impact on it, please submit a comment (see **ADDRESSES**) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding the rule so that they could better evaluate its effects on them and participate in the rulemaking process. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the address listed under **ADDRESSES.** The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247).

Collection of Information

This rule calls for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this rule under that Order and have determined that it does not have implications for federalism.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 or more in any one year.

Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

Taking of Private Property

This rule will not effect a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

Civil Justice Reform

This rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

Protection of Children

We have analyzed this rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and does not create an environmental risk to health or risk to safety that may disproportionately affect children.

Indian Tribal Governments

This rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

Energy Effects

We have analyzed this rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a ''significant energy action'' under that order because it is not a ''significant regulatory action'' under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The Administrator of the Office of Information and Regulatory Affairs has not designated it as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

Technical Standards

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the Office of Management and Budget, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (*e.g.*, specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

This rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

Environment

We have analyzed this rule under Commandant Instruction M16475.lD, which guides the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA)(42 U.S.C. 4321–4370f), and have concluded that there are no factors in this case that would limit the use of a categorical exclusion under section 2.B.2 of the Instruction. Therefore, this rule is categorically excluded, under figure 2–1, paragraph (34)(h), of the Instruction, from further environmental documentation. Special local regulations issued in conjunction with a regatta or marine parade permit are specifically excluded from further analysis and documentation under that section.

List of Subjects in 33 CFR Part 100

Marine safety, Navigation (water), Reporting and recordkeeping requirements, Waterways.

■ For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 100 as follows:

PART 100—SAFETY OF LIFE ON NAVIGABLE WATERS

■ 1. The authority citation for part 100 continues to read as follows:

Authority: 33 U.S.C. 1233; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add temporary § 100.35–T05–051 to read as follows:

§ 100.35–T05–051 Maryland Swim for Life, Chester River, Chestertown, MD.

(a) *Definitions.* (1) *Coast Guard Patrol Commander* means a commissioned, warrant, or petty officer of the Coast Guard who has been designated by the Commander, Coast Guard Sector Baltimore.

(2) *Official Patrol* means any vessel assigned or approved by Commander, Coast Guard Sector Baltimore with a commissioned, warrant, or petty officer on board and displaying a Coast Guard ensign.

(3) *Participant* includes all swimmers and support vessels participating in the Maryland Swim for Life under the auspices of the Marine Event Permit issued to the event sponsor and approved by Commander, Coast Guard Sector Baltimore.

(b) *Regulated area.* The regulated area is established for the waters of the Chester River from shoreline to shoreline, bounded on the south by a line drawn at latitude 39°10′16″ north, near the Chester River Channel Buoy (LLN 26795) and bounded on the north by the Maryland S.R. 213 Highway Bridge. All coordinates reference Datum: NAD 1983.

(c) *Special local regulations.* (1) Except for event participants and persons or vessels authorized by the Coast Guard Patrol Commander, no person or vessel may enter or remain in the regulated area.

(2) The operator of any vessel in the regulated area must:

(i) Stop the vessel immediately when directed to do so by any Official Patrol.

(ii) Proceed as directed by any Official Patrol.

(d) *Enforcement period.* This section will be enforced from 6:30 a.m. to 1:30 p.m. on June 18, 2005.

Dated: June 1, 2005.

Sally Brice-O'Hara,

Rear Admiral, U.S. Coast Guard, Commander, Fifth Coast Guard District.

[FR Doc. 05–11489 Filed 6–9–05; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[CGD01–05–028]

RIN 1625–AA09

Drawbridge Operation Regulations: Housatonic River, CT

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard has temporarily changed the drawbridge operating regulations governing the operation of the US 1 Bridge, mile 3.5, across the Housatonic River at Stratford, Connecticut. Under this temporary rule only one of the two-bascule leafs at the bridge shall open for the passage of vessel traffic from June 18, 2005 through December 30, 2005, except holidays. Two-leaf, full bridge openings, shall be

provided upon a three-day advance notice. This temporary rulemaking is necessary to facilitate rehabilitation repairs at the bridge.

DATES: This rule is effective June 18, 2005, through December 30, 2005.

ADDRESSES: Comments and material received from the public, as well as documents indicated in this preamble as being available in the docket, are part of docket (CGD01–05–028) and are available for inspection or copying at the First Coast Guard District, Bridge Branch Office, 408 Atlantic Avenue, Boston, Massachusetts, 02110, between 7 a.m. and 3 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Ms. Judy Leung-Yee, Project Officer, First Coast Guard District, (212) 668–7165.

SUPPLEMENTARY INFORMATION:

Regulatory Information

On April 19, 2005, we published a notice of proposed rulemaking (NPRM) entitled Drawbridge Operation Regulations, Housatonic River, Connecticut, in the **Federal Register** (70 FR 20322). We received no comments in response to the notice of proposed rulemaking. No public hearing was requested and none was held.

Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**.

The Coast Guard believes making this final rule effective less than 30 days after publication is reasonable because the bridge rehabilitation construction is necessary vital work that needs to be performed as soon as possible.

Any delay in making this final rule effective would not be in the best interest of public or safety because performing this work during the non-winter months June 18, 2005 through December 30, 2005, is the best time period during which construction personnel may work in a more safe and productive manner to help restore the bridge to a safe and reliable operational status.

Background and Purpose

The US 1 Bridge has a vertical clearance in the closed position of 32 feet at mean high water and 37 feet at mean low water. The existing drawbridge operation regulations are listed at 33 CFR § 117.207(a).

The owner of the bridge, the Connecticut Department of Transportation, requested a temporary change to the drawbridge operation regulations to facilitate rehabilitation maintenance at the bridge.

Under this temporary rule only one of the two-bascule leafs at the US 1 Bridge would open for the passage of vessel traffic from June 18, 2005 through December 30, 2005.

The Monday through Friday closures to facilitate vehicular commuter traffic in the existing operation regulations, 7 a.m. to 9 a.m. and 4 p.m. to 5:45 p.m., will continue to be in effect during this temporary rule.

Two-leaf openings will be provided on the following holidays: the Fourth of July, Friday, July 1 through Monday, July 4; Labor Day, Friday, September 2 through Monday, September 5; Thanksgiving, Thursday, November 24 through Sunday, November 27; and Christmas, Saturday, December 24 through Monday, December 26, 2005.

In addition, full two leaf bridge opening will be provided at any time, except during the closed periods for vehicular commuter traffic, after at least a three-day advance notice is given by calling the number posted at the bridge.

Discussion of Comments and Changes

The Coast Guard received no comments in response to the notice of proposed rulemaking. As a result of the above, no changes were made to this temporary final rule.

Regulatory Evaluation

This rule is not a ''significant regulatory action'' under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3), of that Order. The Office of Management and Budget has not reviewed it under that Order. It is not ''significant'' under the regulatory policies and procedures of the Department of Homeland Security (DHS).

This conclusion is based on the fact that the bridge will fully open at any time after a three-day notice is given.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we considered whether this rule would have a significant economic impact on a substantial number of small entities. The term ''small entities'' comprises small businesses, not-for profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations less than 50,000.

The Coast Guard certifies under 5 U.S.C. 605(b), that this rule will not have a significant economic impact on a substantial number of small entities.

This conclusion is based on the fact that the bridge will fully open at any time after a three-day notice is given.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we offered to assist small entities in understanding the rule so that they could better evaluate its effects on them and participate in the rulemaking process.

No small entities requested Coast Guard assistance and none was given.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247).

Collection of Information

This rule calls for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this rule under that Order and have determined that it does not have implications for federalism.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

Taking of Private Property

This rule will not effect a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and

Interference with Constitutionally Protected Property Rights.

Civil Justice Reform

This rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

Protection of Children

We have analyzed this rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and does not concern an environmental risk to health or risk to safety that may disproportionately affect children.

Indian Tribal Governments

This final rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

Energy Effects

We have analyzed this rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a ''significant energy action'' under that order because it is not a ''significant regulatory action'' under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The Administrator of the Office of Information and Regulatory Affairs has not designated it as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

Technical Standards

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the Office of Management and Budget, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (*e.g.*, specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

This rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

Environment

We have analyzed this final rule under Commandant Instruction M16475.1D, which guides the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have concluded that there are no factors in this case that would limit the use of a categorical exclusion under section 2.B.2 of the Instruction. Therefore, this rule is categorically excluded, under figure 2–1, paragraph (32)(e), of the Instruction, from further environmental documentation. It has been determined that this final rule does not significantly impact the environment.

List of Subjects in 33 CFR Part 117

Bridges.

Regulations

■ For the reasons set out in the preamble, the Coast Guard amends 33 CFR part 117 as follows:

PART 117—DRAWBRIDGE OPERATION REGULATIONS

■ 1. The authority citation for part 117 continues to read as follows:

Authority: 33 U.S.C. 499; Department of Homeland Security Delegation No. 0170.1; 33 CFR 1.05–1(g); section 117.255 also issued under the authority of Pub. L. 102–587, 106 Stat. 5039.

2. From June 18, 2005 through December 30, 2005, paragraph (a) in § 117.207 is suspended and a new paragraph (c) is added to read as follows:

§ 117.207 Housatonic River.

* * * * *

(c) From June 18, 2005 through December 30, 2005, the U.S. 1 Bridge, mile 3.5, at Stratford, shall open on signal, except that, it may open only one of the two-bascule leafs for the passage of vessel traffic.

(1) From 7 a.m. to 9 a.m. and 4 p.m. to 5:45 p.m., Monday through Friday, the bridge may remain closed for the passage of vessel traffic.

(2) Two-leaf, full bridge openings, shall be provided on holidays as follows: the Fourth of July, Friday, July 1 through Monday, July 4; Labor Day, Friday, September 2 through Monday, September 5; Thanksgiving, Thursday, November 24 through Sunday, November 27; and Christmas, Saturday, December 24 through Monday, December 26, 2005.

(3) Two-leaf, full bridge openings, shall be provided at any time, except as provided in (c)(1), after at least a three-day advance notice is given by calling the number posted at the bridge.

Dated: May 25, 2005.

David P. Pekoske,

Rear Admiral, U.S. Coast Guard, Commander, First Coast Guard District.

[FR Doc. 05–11487 Filed 6–9–05; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[CGD01–05–034]

RIN 1625–AA09

Drawbridge Operation Regulations: Kennebec River, ME

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard has temporarily changed the drawbridge operating regulations governing the operation of the Carlton Bridge, mile 14.0, across the Kennebec River between Bath and Woolwich, Maine. This temporary final rule allows the bridge to open on signal every three hours at 6 a.m., 9 a.m., 12 p.m., 3 p.m., and 6 p.m., Monday through Saturday, from July 5 through December 17, 2005, and again from April 1 through June 30, 2006, to facilitate rehabilitation construction at the bridge. This rule also allows five three-day bridge closures in September and October of 2005. Vessels that can pass under the bridge without a bridge opening may do so at all times.

DATES: This rule is effective on July 11, 2005 through June 30, 2006.

ADDRESSES: Comments and material received from the public, as well as documents indicated in this preamble as being available in the docket, are part of docket (CGD01–05–034) and are available for inspection or copying at the First Coast Guard District, Bridge Branch Office, 408 Atlantic Avenue, Boston, Massachusetts, 02110, between 7 a.m. and 3 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Ms. Judy Leung-Yee, Project Officer, First Coast Guard District, (212) 668–7165.

SUPPLEMENTARY INFORMATION:

Regulatory Information

On April 20, 2005, we published a notice of proposed rulemaking (NPRM) entitled Drawbridge Operation Regulations, Kennebec River, Maine, in the **Federal Register** (70 FR 20490). We received no comments in response to the notice of proposed rulemaking. No public hearing was requested and none was held.

Background and Purpose

The Carlton Bridge has a vertical clearance of 10 feet at mean high water and 16 feet at mean low water in the closed position. The existing drawbridge operation regulations are listed at 33 CFR 117.525.

The owner of the bridge, Maine Department of Transportation (MDOT), requested a temporary change to the drawbridge operation regulations to allow the bridge to open on signal every three hours at 6 a.m., 9 a.m., 12 p.m., 3 p.m., and 6 p.m., only, Monday through Saturday, from July 5 through December 17, 2005, and again from April 1 through June 30, 2006, to facilitate rehabilitation construction at the bridge.

From 6 p.m. through 6 a.m. the draw shall open on signal after at least a two-hour notice is given by calling the number posted at the bridge.

The bridge shall open on signal for Labor Day weekend, Friday, September 2, 2005 through Monday, September 5, 2005, from 8 a.m. to 5 p.m., and from 5 p.m. through 8 a.m., the draw shall open after a two-hour notice is given by calling the number posted at the bridge.

From December 18, 2005 through March 31, 2006, the bridge shall operate in accordance with its normal winter schedule.

In addition, this temporary final rule allows five three-day bridge closures as follows: September 7 through September 9; September 20 through September 22; October 4 through October 6; October 18 through October 20; and November 1 through November 3, 2005.

Discussion of Comments and Changes

The Coast Guard received no comments in response to the notice of proposed rulemaking. We have changed the start date of the rule, from July 5, 2005, to July 11, 2005, to ensure that a full 30 days notice is provided to the public after publication of this rule.

Regulatory Evaluation

This rule is not a ''significant regulatory action'' under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3), of that Order. The Office of Management and Budget has not reviewed it under that Order. It is not ?significant? under the regulatory policies and procedures of the Department of Homeland Security (DHS).

This conclusion is based on the fact that the bridge will continue to open on signal for all vessels at three-hour intervals from 6 a.m. to 6 p.m.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we considered whether this rule would have a significant economic impact on a substantial number of small entities. The term ''small entities'' comprises small businesses, not-for profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations less than 50,000.

The Coast Guard certifies under 5 U.S.C. 605(b), that this rule will not have a significant economic impact on a substantial number of small entities.

This conclusion is based on the fact that the bridge will continue to open on signal for all vessel traffic at three-hour intervals from 6 a.m. to 6 p.m.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we offered to assist small entities in understanding the rule so that they could better evaluate its effects on them and participate in the rulemaking process.

No small entities requested Coast Guard assistance and none was given.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency?s responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247).

Collection of Information

This rule calls for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this rule under that Order and have determined that it does not have implications for federalism.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

Taking of Private Property

This rule will not effect a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

Civil Justice Reform

This rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

Protection of Children

We have analyzed this rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and does not concern an environmental risk to health or risk to safety that may disproportionately affect children.

Indian Tribal Governments

This final rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

Energy Effects

We have analyzed this rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a ''significant

energy action'' under that order because it is not a ''significant regulatory action'' under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The Administrator of the Office of Information and Regulatory Affairs has not designated it as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

Technical Standards

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the Office of Management and Budget, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (*e.g.*, specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

This rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

Environment

We have analyzed this final rule under Commandant Instruction M16475.1D, which guides the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have concluded that there are no factors in this case that would limit the use of a categorical exclusion under section 2.B.2 of the Instruction. Therefore, this rule is categorically excluded, under figure 2–1, paragraph (32)(e), of the Instruction, from further environmental documentation. It has been determined that this final rule does not significantly impact the environment.

List of Subjects in 33 CFR Part 117

Bridges.

Regulations

■ For the reasons set out in the preamble, the Coast Guard amends 33 CFR part 117 as follows:

PART 117—DRAWBRIDGE OPERATION REGULATIONS

■ 1. The authority citation for part 117 continues to read as follows:

Authority: 33 U.S.C. 499; Department of Homeland Security Delegation No. 0170.1; 33 CFR 1.05–1(g); section 117.255 also issued under the authority of Pub. L. 102–587, 106 Stat. 5039.

■ 2. From July 5, 2005 through June 30, 2006, § 117.525(a) is suspended and a new paragraph (c) is added to read as follows:

§ 117.525 Kennebecc River.

* * * * *

(c) (1) The Carlton Bridge, mile 14.0, shall open on signal at 6 a.m., 9 a.m., 12 p.m., 3 p.m., and 6 p.m., Monday through Saturday, from July 5, 2005 through December 17, 2005, and from April 1, 2006 through June 30, 2006. From 6 p.m. through 6 a.m. the draw shall open on signal after at least a two-hour notice is given by calling the number posted at the bridge.

(2) The draw shall open on signal on Labor Day weekend, Friday, September 2, 2005 through Monday, September 5, 2005, from 8 a.m. to 5 p.m., and from 5 p.m. through 8 a.m., the draw shall open after a two-hour notice is given by calling the number posted at the bridge.

(3) From December 18, 2005 through March 31, 2006, the bridge shall open on signal, except that, from 5 p.m. to 8 a.m., the draw would open on signal after a twenty-four hour notice is given and from 8 a.m. to 5 p.m., on Saturday and Sunday, after an eight-hour notice is given by calling the number posted at the bridge.

(4) The draw of the Carlton Bridge may remain in the closed position for five three-day closure periods as follows: September 7 through September 9; September 20 through September 22; October 4 through October 6; October 18 through October 20; and November 1 through November 3, 2005.

Dated: May 25, 2005.

David P. Pekoske,

Rear Admiral, U.S. Coast Guard, Commander, First Coast Guard District.

[FR Doc. 05–11486 Filed 6–9–05; 8:45 am]

BILLING CODE 4910–15–P

POSTAL SERVICE

39 CFR Part 111

Premium Forwarding Service

AGENCY: Postal Service.

ACTION: Final rule.

SUMMARY: This final rule sets forth the standards adopted by the Postal Service™ to implement the Premium Forwarding Service (PFS) experiment.

The Postal Service is conducting the PFS experiment to measure interest in a new service that forwards mail to residential customers who are temporarily away from their primary address. With PFS, your local Post Office will ship mail to your temporary address once a week via Priority Mail®.

DATES: *Effective Date:* This final rule is effective at 12:01 a.m. on August 7, 2005.

FOR FURTHER INFORMATION CONTACT: Rick Klutts, 202–268–7268.

SUPPLEMENTARY INFORMATION: Today, customers can submit a temporary forwarding request for their First-Class Mail and Periodicals mail. Customers also can have their mail held at the Post Office for short periods of time. Premium Forwarding Service (PFS) is a two-year, nationwide experiment that reships all of a customer's mail on a weekly basis.

PFS is a personalized service designed for sending mail from a customer's primary residential address to a temporary address using Priority Mail. With PFS, the Postal Service boxes and ships mail to customers who are away for at least two weeks and up to one year.

Express Mail and Priority Mail packages that are too large to fit inside the weekly PFS package are immediately and separately rerouted at no additional charge. Package Services parcels that are too large to fit inside the PFS package are forwarded with postage due. All mail requiring a delivery scan or a signature also is separately rerouted. Examples include Certified Mail, Registered Mail, and mail with Delivery Confirmation.

PFS generally provides a shipment of a customer's mail every Wednesday from their primary address to their temporary address by Priority Mail. There is an initial enrollment fee of $10, plus a weekly per-shipment charge of $10.

Customers who wish to participate must submit an application to the Post Office responsible for delivery to their primary address and pay the enrollment fee and shipment charges for the full duration they will be away. The minimum enrollment is two weeks, and the maximum is one year.

Customers who wish to cancel PFS early may request a refund for any unused weekly shipment charges from the Post Office serving their primary address. Additionally, customers can contact that Post Office prior to the termination date to extend PFS service (up to one year total) as needed.

The Board of Governors of the United States Postal Service approved the PFS experiment on May 10, 2005. The standards, which will be incorporated into *Mailing Standards of the United*

States Postal Service, Domestic Mail Manual (DMM®) are included in the Opinion and Recommended Decision of the Postal Rate Commission Approving Stipulation and Agreement for Experimental Premium Forwarding Service, Docket No. MC2005–1.

The mailing standards for the two-year Premium Forwarding Service experiment are provided below.

The Postal Service is making the following amendments to *Mailing Standards of the United States Postal Service*, Domestic Mail Manual (DMM), which is incorporated by reference in the *Code of Federal Regulations* (*see* 39 CFR 111).

List of Subjects in 39 CFR Part 111

Administrative practice and procedure, United States Postal Service.

PART 111—[AMENDED]

■ 1. The authority citation for 39 CFR Part 111 continues to read as follows:

Authority: 5 U.S.C. 552(a); 39 U.S.C. 101, 401, 403, 404, 414, 3001–3011, 3201–3219, 3403–3406, 3621, 3626, 5001.

■ 2. Revise the following sections of the DMM, as set forth below:

700 Special Standards

* * * * *

709 Experimental Classifications and Rates

* * * * *

[Add new 709.8.0 to read as follows:]

8.0 Premium Forwarding Service

8.1 Description and Purpose

Premium Forwarding Service (PFS) is a 2-year experiment that, upon payment of postage and fees, provides residential delivery customers and certain post office box customers an option to have all mail addressed to their primary address reshipped or rerouted to a temporary address mainly by means of a weekly Priority Mail shipment. PFS is available for a period of not less than 2 weeks and not more than 1 year. This optional service is in addition to the current piece-by-piece forwarding service currently offered by USPS, whereby only certain mailpieces are forwarded.

8.2 Eligibility

8.2.1 Use

Participation in PFS is subject to the following standards:

a. PFS is available to residential delivery customers and all size-one or size-two post office box customers.

b. A customer must submit a completed PFS application, Form 8176, to the post office (or a station or branch of that post office) responsible for delivery to the customer's primary address. The enrollment fee and reshipment charges for the full duration of requested service must accompany the application form.

c. Customers must designate on the application form whether the order is for an ''individual'' or an ''entire household.''

d. PFS is available for a period of not less than 2 weeks and not more than 1 year.

e. PFS is available only from and to domestic addresses.

f. PFS is available to, but not from, central point delivery addresses, APO and FPO addresses, and U.S. State Department addresses.

8.2.2 Prohibited Use

Customers cannot have a temporary or permanent forwarding order active simultaneously with enrollment in PFS. PFS cannot be combined with any ancillary or extra services beyond those purchased by the original sender. In addition, PFS is not available for:

a. Customers whose primary address is a size-three, size-four, or size-five post office box. Residential customers who use these post office box sizes due to the unavailability of smaller boxes may request a waiver of this restriction.

b. Customers whose primary address is a business delivery address.

c. Customers whose primary address is a central point to which the USPS provides delivery in bulk to a third party, such as a commercial mail receiving agency (CMRA), RV park, trailer park, or hotel.

8.3 Rates and Fees

8.3.1 Enrollment

Customers must pay a $10.00 nonrefundable enrollment fee.

8.3.2 Charge Per Reshipment

The reshipment charge for each Priority Mail shipment is $10.00 for each week of service requested.

8.4 Extension or Early Termination

8.4.1 Early Termination of Service

A customer who terminates PFS early (*e.g.*, a customer prepays for 10 weeks but returns to a primary address after 8 weeks) may request a refund for any unused weekly shipment charges from the post office serving the primary address. The enrollment fee is nonrefundable.

8.4.2 Extension of Service

A PFS customer may contact the post office responsible for delivery to the primary address prior to the termination date and extend PFS service (up to 1 year maximum service from the initial start date) as needed. An extension is processed only after the post office receives payment of all postage and fees for the extension.

8.5 Disposition of PFS Mail

8.5.1 Weekly Priority Mail Reshipments

Regardless of any endorsement on a mailpiece, all mail is reshipped in the weekly Priority Mail shipment, except as specified below.

8.5.2 Mailpieces Requiring a Scan or Signature at Delivery

Mailpieces requiring a scan or signature at delivery (*e.g.*, Express Mail, Certified Mail, numbered insured mail, mailpieces with Delivery Confirmation) are appropriately scanned, then immediately and separately rerouted to the temporary address, subject to the following:

a. Express Mail, Priority Mail, and First-Class Mail are rerouted at no additional charge.

b. Standard Mail and Package Services mailpieces are rerouted postage due at the appropriate Priority Mail rate.

8.5.3 Priority Mail Not Requiring a Scan or Signature at Delivery

Priority Mail that does not require a scan or signature at delivery is immediately and separately rerouted to the temporary address, unless it will fit into the weekly Priority Mail shipment and such inclusion does not delay its delivery to the temporary address.

8.5.4 Large Packages Not Requiring a Scan or Signature at Delivery

Packages that do not fit into the weekly Priority Mail shipment and do not require a scan or signature at delivery are separately rerouted to the temporary address, subject to the following:

a. First-Class Mail and Periodicals parcels (firm bundles) are rerouted at no additional charge.

b. Standard Mail and Package Services parcels are rerouted postage due at the appropriate Priority Mail rate.

c. Oversized Parcel Post parcels are rerouted postage due at the appropriate oversized Parcel Post rate.

8.5.5 Mailpieces Arriving Postage Due at the Primary Address

Any mailpiece arriving postage due at the post office serving a PFS customer's primary address is not reshipped in the weekly Priority Mail shipment and will be rerouted individually. Pieces arriving postage due are rerouted as follows:

a. Postage due First-Class Mail pieces are rerouted as First-Class Mail postage due. Only the original postage due amount is collected. There is no additional charge for rerouting the mailpiece.

b. Postage due Priority Mail pieces are rerouted as Priority Mail postage due. Only the original postage due amount is collected. There is no additional charge for rerouting the mailpiece.

c. Postage due for all Package Services pieces, other than oversized Parcel Post pieces, are rerouted as Priority Mail. The total postage due for Package Services pieces is the sum of the postage due at the time of receipt at the primary post office plus the postage due for rerouting the piece from the primary post office to the temporary post office at the appropriate Priority Mail rate.

d. Postage due oversized Parcel Post pieces are rerouted as Parcel Post. The total postage due is the sum of the postage due at the time of receipt at the primary post office and the postage due for rerouting the piece from the primary post office to the temporary post office at the appropriate oversized Parcel Post rate.

8.6 USPS Responsibility

The delivery post office serving a PFS customer's primary address must:

a. Prepare and send the PFS shipments once each week, on Wednesdays.

b. Ensure that PFS shipments end in accordance with the original or revised end date specified on the application form, and that delivery to the primary address begins (or holding mail commences under 507.3.4.4) as designated by the customer.

c. Ensure that Label 85 (Permit No. G–400) is properly affixed to each reshipped PFS Priority Mail package. Postage meter or PVI postage must not be affixed.

* * * * *

Neva R. Watson,

Attorney, Legislative.

[FR Doc. 05–11472 Filed 6–9–05; 8:45 am]

BILLING CODE 7710–12–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 51 and 52

[FRL–7923–3; E–Docket ID No. OAR–2002–0068]

RIN 2060–AM58

Prevention of Significant Deterioration (PSD) and Non-attainment New Source Review (NSR): Equipment Replacement Provision of the Routine Maintenance, Repair and Replacement Exclusion: Reconsideration

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of final action on reconsideration.

SUMMARY: On October 27, 2003, and December 24, 2003, the EPA revised regulations governing the major New Source Review (NSR) programs mandated by parts C and D of title I of the Clean Air Act (CAA or Act). The rule changes from October 27, 2003, provide a category of equipment replacement activities that are deemed to be routine maintenance, repair and replacement (RMRR) activities and, therefore, are not subject to Major NSR requirements under the exclusion, while the December 24, 2003 rule changes amended the Prevention of Significant Deterioration (PSD) provisions of state programs that did not have approved state rules for PSD. Also on December 24, 2003, the U.S. Court of Appeals for the District of Columbia Circuit stayed the new RMRR rules, pending judicial review. Following these actions, the Administrator received petitions for reconsideration. On July 1, 2004, we, the EPA, announced our reconsideration of certain issues arising from these two final rules and requested comment on those issues. After carefully considering all of the comments and information received through our reconsideration process, we have concluded that no additional changes are necessary to the final rules. With respect to all other issues raised by the petitioners, we deny the requests for reconsideration.

DATES: This final action is effective on June 10, 2005.

ADDRESSES: EPA has established a docket for this action under Docket ID No. OAR–2002–0068 (Legacy Number A–2002–04). All documents in the docket are listed in the index. Although listed in the index, some information is not publicly available, *i.e.*, CBI or other information whose disclosure is restricted by statute. Publicly available docket materials are available in hard copy either electronically in the EDOCKET at *http://www.epa.gov/edocket* or in hard copy at the U.S. Environmental Protection Agency, EPA West (Air Docket), 1200 Pennsylvania Avenue, Northwest, B102, Mail code: 6102T, Washington, DC 20460, Attention Docket ID No. OAR–2002–0068, Washington, DC 20004. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the Docket is (202) 566–1742.

FOR FURTHER INFORMATION CONTACT: Mr. David J. Svendsgaard, Information Transfer and Program Integration Division (C339–03), U.S. Environmental Protection Agency, Research Triangle Park, NC 27711, telephone number: (919) 541–2380; fax number: (919) 541–5509, or electronic mail at *svendsgaard.dave@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. What are the Regulated Entities?

Entities potentially affected by the subject rule for today's action include sources in all industry groups. The majority of sources potentially affected are expected to be in the following groups.

Industry group	SIC [a]	NAICS [b]
Electric Services	491	221111, 221112, 221113, 221119, 221121, 221122.
Petroleum Refining	291	324110.
Industrial Inorganic Chemicals	281	325181, 325120, 325131, 325182, 211112, 325998, 331311, 325188.
Industrial Organic Chemicals	286	325110, 325132, 325192, 325188, 325193, 325120, 325199.
Miscellaneous Chemical Products	289	325520, 325920, 325910, 325182, 325510.
Natural Gas Liquids	132	211112.
Natural Gas Transport	492	486210, 221210.
Pulp and Paper Mills	261	322110, 322121, 322122, 322130.
Paper Mills	262	322121, 322122.
Automobile Manufacturing	371	336111, 336112, 336211, 336992, 336322, 336312, 336330, 336340, 336350, 336399, 336212, 336213.

Industry group	SIC [a]	NAICS [b]
Pharmaceuticals	283	325411, 325412, 325413, 325414.

[a] Standard Industrial Classification.
[b] North American Industry Classification System.

Entities potentially affected by the subject rule for today's action also include State, local, and tribal governments.

B. How Is This Preamble Organized?

The information presented in this preamble is organized as follows:

I. General Information
A. What are the regulated entities?
B. How is this preamble organized?
II. Background
III. Today's Action
A. Three Issues for Which Reconsideration Was Granted
1. Legal Basis
2. The 20 Percent Replacement Cost Threshold
3. Revisions to the Format for Incorporating the PSD FIP into State Plans
B. Remaining Issues in Petitions for Reconsideration
1. Petitioners' claim that EPA retroactively applied the ERP
2. Petitioners' claim that EPA cannot modify a State's SIP without a finding of deficiency
IV. Statutory and Executive Order Reviews
A. Executive Order 12866—Regulatory Planning and Review
B. Paperwork Reduction Act
C. Regulatory Flexibility Act
D. Unfunded Mandates Reform Act
E. Executive Order 13132—Federalism
F. Executive Order 13175—Consultation and Coordination with Indian Tribal Governments
G. Executive Order 13045—Protection of Children from Environmental Health & Safety Risks
H. Executive Order 13211—Actions That Significantly Affect Energy Supply, Distribution, or Use
I. National Technology Transfer and Advancement Act
J. Congressional Review Act
V. Statutory Authority
VI. Judicial Review

II. Background

On October 27, 2003, we published the Equipment Replacement Provision (''ERP'') amendments to our regulations implementing the major NSR requirements of the CAA.[1] The ERP amended the exclusion from major NSR for ''routine maintenance, repair, and replacement'' (''RMRR'') activities at existing major sources. Several parties sought judicial review of the ERP in the U.S. Court of Appeals for the District of Columbia Circuit. *See State of New York* v. *EPA*, No. 03–1380 and consolidated cases (DC Cir.). As a result of a court order, the ERP is ''stayed'' (*i.e.*, not in effect) until the court decides this case.

On December 24, 2003, EPA published a rule amending the Prevention of Significant Deterioration (PSD) provisions of state programs that did not have approved state rules for PSD. 68 FR 74483. In each of these states, EPA previously had made the area subject to the PSD rules in 40 CFR 52.21, the Federal Implementation Plan (''FIP'') for PSD. Please see 68 FR 74483 (December 24, 2003), for additional background on this rule. Parties have also sought judicial review of this rule, and their petitions for review have been consolidated with the challenges to the ERP.

Also on December 24, 2003, a group of environmental organizations [2] petitioned EPA, pursuant to section 307(d)(7)(B) of the CAA, to reconsider three aspects of the Equipment Replacement Provision that we published on October 27, 2003. Specifically, the petitioners [3] asserted that our legal basis for the ERP is flawed, the basis for the 20 percent ERP cost threshold is arbitrary and capricious, and EPA has retroactively applied the ERP.

On January 16, 2004, a subset of the environmental petitioners on the ERP rule filed a petition for reconsideration of the December 24, 2003 rule that incorporated the ERP into the FIP portion of a State plan where the State does not have an approved PSD State Implementation Plan (SIP). This petition reiterated the issues raised in the December 24, 2003 petition concerning the ERP. On February 23, 2004, a group of states and the District of Columbia [4] filed a petition for reconsideration of the December 24, 2003 rule. This petition raised two issues. First, it asked for reconsideration on whether EPA needed to make a finding of deficiency for the PSD portions of each SIP before it amended the incorporation of the PSD FIP into the state plans. Second, it challenged whether EPA needed to provide an opportunity for comment on the revised format for incorporating the PSD FIP into state plans, which would automatically update the state plans whenever EPA amends the PSD FIP.

On July 1, 2004 (69 FR 40278), we granted reconsideration and requested comment on three issues raised by petitioners—specifically, the contentions that our legal basis is flawed, that our selection of 20 percent for the cost limit is arbitrary and capricious and lacks sufficient record, and that we should provide an opportunity for comment on the revised format for incorporating the PSD FIP into state plans. We decided to grant reconsideration on these issues because of the importance EPA attaches to ensuring that all have ample opportunity to comment. At that time, we did not act on the remaining two issues in those petitions.

On August 2, 2004, we held a public hearing on the issues for which we granted reconsideration. Five individuals gave oral presentations at the hearing. The transcript of their comments is located in Docket OAR–2002–0068 (Legacy Number A–2002–04), which can be accessed on the Internet at *http://www.epa.gov/edocket.*

The public comment period on the reconsideration issues ended on August 30, 2004, and we allowed until September 1, 2004 to receive public comments for issues arising out of the August 2nd public hearing. More than 350 written public comments on the reconsideration issues were received. The individual comment letters can be found in Docket OAR–2002–0068 (Legacy Number A–2002–04).

III. Today's Action

At this time, we are announcing our final action on reconsideration of the three issues for which we asked for comment in our July 1, 2004 notice. We

[1] The October 27, 2003 final rule did not act on the ''Annual Maintenance, Repair and Replacement Allowance'' approach that we proposed on December 31, 2002 (67 FR 80920). We may act on this portion of the 2002 proposal in a subsequent rulemaking.

[2] The following parties filed the petition for reconsideration of the October 27, 2003 rule: Natural Resources Defense Council, Environmental Defense, Sierra Club, American Lung Association, Communities for a Better Environment, United States Public Interest Research Group, Alabama Environmental Council, Clean Air Council, Group Against Smog and Pollution, Michigan Environmental Council, The Ohio Environmental Council, Scenic Hudson, and Southern Alliance for Clean Energy.

[3] In this notice, the term ''petitioner'' refers only to those entities that filed petitions for reconsideration with EPA.

[4] The states that filed a petition for reconsideration of the December 24, 2003 rule are California, Connecticut, Illinois, Massachusetts, New Jersey, and New York, along with the District of Columbia.

are also announcing our final decision on the remaining two issues that were raised by the petitioners. We are making available a document entitled, ''Technical Support Document for the Equipment Replacement Provision of the Routine Maintenance, Repair and Replacement Exclusion: Reconsideration,'' EPA 456/R–05–003. This document contains (1) a summary of comments received on the issues for which we granted reconsideration and our responses to these comments, and (2) a summary of petition issues for which we are not granting reconsideration, and our rationale for denying reconsideration. This document is available on our Web site at *http://www.epa.gov/nsr/*; and, through the National Technical Information Services, 5285 Port Royal Road, Springfield, VA 22161; telephone (800) 553–6846, e-mail *http://www.ntis.gov*; and, from the U.S. EPA, Library Services, MD C267–01, Research Triangle Park, NC 27711, telephone (919) 541–2777, e-mail *library.rtp@epa.gov*.

A. Three Issues for Which Reconsideration Was Granted

1. Legal Basis

Our July 1, 2004 notice noted that underlying our legal rationale for the ERP is a basic tenet of administrative law stated in *Chevron, U.S.A., Inc.* v. *NRDC*, 467 U.S. 837 (1984). The *Chevron* Court held that expert agencies have the discretion to reasonably interpret ambiguous statutory terms and that such interpretations are due deference. *Id.* at 842–845. In the October 27, 2003 final rule and in the July 1, 2004 notice, we explained that the statutory definition of 'modification,' CAA 111(a)(4), and, in particular, the word ''change'' in the phrase ''any physical change or change in the method of operation,'' is ambiguous. The word itself is ambiguous, and the use of ''any'' as a modifier, in the context of the statute, simply requires EPA to include an indeterminate number of changes as potential modifications [5] once EPA defines the ambiguous term ''change.'' The ERP, which establishes criteria for determining what equipment replacement activities do not constitute physical changes, is a rational interpretation of ''physical change'' in the definition of ''modification.'' See 68 FR 61268–61274 for our more detailed legal support for the ERP.

In granting reconsideration, we invited comments on several legal arguments suggested by commenters on the meaning of the statutory definition of ''modification.'' In particular, we noted that commenters had suggested that the plain meaning of the ''modification'' definition required that functionally equivalent equipment replacements not be deemed to be changes and, therefore, be deemed RMRR. We also noted that other commenters took the opposite view about the plain meaning of the statute. Both sides of this argument cited the principle from *Chevron* that where the statute's meaning is clear, the agency must give its meaning effect (the first step in statutory analysis under *Chevron*, or *Chevron 1*). Some commenters had argued that only *de minimis* exceptions could be allowed under the statute. Others had pointed out that a recognized principle of administrative law allows an agency to establish ''bright line'' criteria to reduce regulatory burden and provide certainty. We invited comment on these arguments and any other possible legal arguments when we granted reconsideration on the issue of whether our legal basis in the ERP was flawed.

We received a number of comments supporting and opposing the legal basis for our rule. Commenters renewed and expanded prior arguments that the definition of ''modification'' was clear and either prohibited or compelled treating like-kind replacements as physical changes when replacement resulted in a potential emissions increase. Some comments, summarized below, addressed Congressional intent as construed by courts, provided specific textual analysis of the modification definition, and offered policy objections to the ERP. We discuss significant comments below and refer you to the TSD for this action for additional discussion of comments and responses.

a. *Congressional Intent.* Commenters assert that the ERP is contrary to Congressional intent and the decision in *Alabama Power* v. *Costle*, 636 F.2d 323 (D.C. Cir. 1979). They characterize the opinion as holding that Congressional intent behind the modification provision was to include any physical change that increases emissions, even though it would undoubtedly prove inconvenient and costly to affected industries. They cite a portion of the opinion that declared, ''the term 'modification' is nowhere limited to physical changes that exceed a certain magnitude.'' Additionally, they claim the Court found EPA's authority to exempt activity from ''modification'' was limited to *de minimis* activity. *Id.* at 400.

We disagree with the commenters' reading of *Alabama Power. Alabama Power* does not directly address whether like-kind replacements must be deemed to be physical changes. The *Alabama Power* Court addressed an exemption for physical changes that resulted in an emissions increase of less than 100 tons. It is in this context, where the replacement activity has been conceded to be a physical change, that the court states that the modification definition ''is nowhere limited to physical changes that exceed a certain magnitude.'' *Alabama Power*, 636 F.2d at 400. In context, the ''magnitude'' language only addresses the size of the emission tonnage increase resulting from a ''change,'' once the activity meets the definition of a ''change.'' The Court did not have before it the question of whether the phrase ''any physical change'' is ambiguous. Contrary to the commenter's assertions, the cited portion of the *Alabama Power* opinion discusses a *de minimis* exemption only in the context of emission increases and not in terms of what constitutes a physical change (''EPA does have the discretion * * * to exempt from PSD review some emission increases on grounds of *de minimis* or administrative necessity''). *Id.*

Moreover, the *Alabama Power* Court also expresses the expectation that ''bubbling'' (or netting) in calculating emission increases and an allowance for physical changes that result in *de minimis* increases in emissions ''will allow for improvement of plants, technological changes, and *replacement of depreciated capital stock*, without imposing a completely disabling administrative and regulatory burden.'' *Alabama Power*, 636 F.2d at 400. (emphasis added). Our subsequent experience has shown that, even with netting, a definition of ''physical change'' as encompassing as that supported by these commenters is inadequate to allow for appropriate replacement of depreciated capital stock. See ''New Source Review: Report to the President'', June 2002 (Docket No. OAR–2002–0068, Document No. 0004). It simply is not the case that the *Alabama Power* opinion analyzes and requires the commenters' encompassing construction of ''any physical change.'' Equally important, a narrow interpretation of ERP as advocated by commenters would create hurdles for ensuring that a process operates reliably, safely, and efficiently, thereby increasing the likelihood that net emissions would be higher.

[5] A physical change would be a modification only if it resulted in a significant emissions increase as we define the term.

The commenters point to several enforcement filings and other EPA pronouncements prior to promulgation of the ERP in which we said the definition of modification was unambiguous and had broad application. Furthermore, they note that we repeatedly recognized that the structure of the Act demonstrates that Congress intended grandfathering to be of limited duration.

We recognize that, prior to promulgation of the ERP, we had not specifically asserted that our interpretation of ''change'' and the exclusions from NSR are based on an exercise of *Chevron* discretion. In some instances, such as in a decision of the Environmental Appeals Board (EAB), *In re: Tennessee Valley Authority*, 9 E.A.D. 357 (EAB 2000), and in briefs in various enforcement-related cases, we had interpreted ''change'' such that virtually all changes, even trivial ones, were encompassed by the Act. Thus, we generally had interpreted the exclusion as being limited to *de minimis* circumstances. However, in the ERP we asserted that EPA does have the authority to interpret these key terms through rulemaking. Upon further consideration of the history of our actions, the statute, and its legislative history, we said that we believe a different view is permissible, and, for policy reasons discussed in the ERP final rule, more appropriate. Therefore, we adopted our *Chevron*-based interpretation of the statute prospectively in the ERP final rule.[6]

Subsequent to promulgating the ERP, we filed court papers noting that, as of the date of the final ERP rule, we adopted a new interpretation of the statute. Our position is most clearly spelled out in a filing we made in *United States* v. *Illinois Power Co., et al.*, Civil Action No. 99–833 (S.D. Ill.) (''Illinois Power''). As we stated to the *Illinois Power* Court, ''the United States does not rely on any prior statements * * * that a very narrow construction of the ''routine maintenance'' exemption is required by the Clean Air Act itself. Instead, the United States will continue to rely on EPA's narrow interpretation of its prior ''routine maintenance'' exception, which remains applicable to this action.'' *Illinois Power*, Plaintiff's Reply to Defendants' Proposed Findings of Fact and Conclusions of Law (Liability Phase) at 5. We no longer interpret the language or structure of the NSR provisions of the Act as an expression of Congress's intent to limit ''grandfathering'' through the indirect means of the ''modification'' provision rather than through other provisions that clearly can reach all existing sources. See, *e.g.*, CAA section 110 (SIP provisions); CAA section 112 (hazardous air pollutant provisions); CAA sections 401–416 (acid rain provisions).

Finally, one group of commenters argues that Congress's decision in 1977 to cross-reference the preexisting definition of ''modification'' in CAA section 111(a)(4) when it adopted the modification provision for NSR should have no impact on assessing whether the terms of the definition are ambiguous. They cite EPA's arguments in our August 2004 brief in *State of New York* v. *EPA*, D.C. Cir. Case No. 02–1387, which refuted arguments that EPA is compelled to interpret both the NSPS and the NSR modification provisions the same way. They construe the ''legal basis'' discussion in our October 27, 2003, ERP final rule as arguing that Congress ratified our ERP interpretation when it enacted the 1977 amendments.

We disagree with the characterization of our argument in the October 27, 2003 preamble to the final ERP rule. Nowhere in that notice do we argue that Congress mandated adoption of the 1977 NSPS regulatory interpretation of what is a ''modification'' when it cross-referenced the definition in CAA 111(a)(4) into the NSR program. As we discussed in the cited passages of our briefs, we do not believe Congress intended to ratify the then-existing interpretation or ''congeal'' our NSR regulations as they stood under the NSPS program in 1977. Our discussion of the history of our interpretation of CAA 111(a)(4) simply points out the obvious: that words of CAA 111(a)(4) historically have been taken to have quite different meanings in the NSR and NSPS programs. From this, we argue that any words that can be given such divergent meanings for decades cannot have but one clear meaning on their face. To argue that the definition of ''modification'' in CAA 111(a)(4) is unambiguous, as the commenters have, one must advance an unusual position: that the same words, with no further definitions or legislative history, facially and unambiguously mean different things.

b. *Textual analysis of the modification definition.* It is axiomatic that the most clear expression of what Congress intended by the ''modification'' definition is in the words it chose to use. Many significant comments we received analyzed the structure of the definition and particular words and phrases in it.

One commenter argued that the statutory term ''modification'' itself is not ambiguous, so the definition of modification should not be read to create ambiguity in the term. The commenter, who argued that the ERP is too generous in excluding equipment replacements from NSR, observed that the plain meaning of modification connotes moderate, as opposed to fundamental, change.

We disagree with the assertion that the ERP allows for ''fundamental'' change in an emission source. In focusing on the 20 percent criterion of the ERP, the commenter ignores other important criteria under the ERP that would, in any ordinary sense of the term, prohibit the possibility of fundamental change as a result of activities that meet the ERP exclusion. A source that maintains its basic design parameters is not fundamentally changed, nor is a source that replaces one piece of equipment with another that is functionally equivalent. Thus, the ERP does not allow for fundamental change of the type the commenter suggests that the term ''modification'' should prohibit. In fact, to clarify this, the ERP explicitly precludes activities that would change the basic design parameters from qualifying for a RMRR exclusion.

Moreover, we disagree with the commenter's assertion that the term ''modification'' itself is unambiguous and in no need of further clarification. In fact, we note that over the years permitting authorities have had to respond to numerous queries regarding whether certain activities constitute a ''modification,'' a testament that there is considerable ambiguity surrounding this term. Apparently, Congress agrees with our view, because it supplied further definition in CAA 111(a)(4).

Many of the comments focused on the significance of the modifier ''any'' in ''any physical change or change in the method of operation.'' In our October 27, 2003 final rule, we said that the word ''any'' did not compel EPA to define what constitutes a ''physical change'' to include all activities that could conceivably be defined as a physical change. In our view, we had discretion to define what activities were

[6] We noted in the ERP final rule: We have taken positions in numerous court filings concerning the proper interpretation and usage of key statutory terms, such as ''physical change'' and ''any physical change.'' These positions were based on permissible constructions of the statute of which the regulated community had fair notice, and correctly reflect the Agency's reasonable accommodation of the Clean Air Act's competing policies in light of its experience at the time it adopted the RMRR exclusion in 1980. The Agency has sought, and has obtained, deference for its interpretations, and, notwithstanding today's adoption of a revised interpretation of the statute and an expansion of the RMRR exclusion, the Agency shall continue to seek deference for those prior interpretations in ongoing enforcement litigation. 68 FR at 61272, fn 14.

physical changes, and once we defined physical change, ''any'' simply meant that any activity that met our definition of physical change could be a modification if it also increased net emissions.

In our July 1, 2004 notice, we invited comment on a recent Supreme Court case that construed a prohibition on states and localities enacting legislation to bar ''any entity'' from offering interstate telecommunications services to not apply to legislation that restrained political subdivisions of states from entering the field. *Nixon* v. *Missouri Municipal League*, 541 U.S. 125, 124 S. Ct. 1555, 1559–60 (2004). The *Nixon* Court observed that Congress's understanding of ''any'' can differ depending upon the statutory setting. *Id.* at 1561. This opinion reversed a case litigants had relied upon in seeking a stay of the ERP on the proposition for which it was cited.[7]

In discussing the significance of the modifier ''any'' in the statute and in discussing the *Nixon* case, commenters opposed to the ERP argued that numerous cases besides *Nixon* have held that terms modified by the word ''any'' must be given the most inclusive meaning possible, that such terms must be interpreted expansively, and that ''any'' has a broad meaning.[8] These commenters distinguished Nixon on the grounds that this case raised peculiar federalism concerns (*i.e.*, the ability of a state to regulate its own political subdivisions) not present in CAA 111(a)(4) or the ERP.

Several other precedents establish that the principle on which *Nixon* relies, that the understanding of ''any'' can depend on the statutory context, is not limited to situations with federalism implications. *E.g., O'Connor* v. *U.S.*, 479 U.S. 27, 31 (1986) (statutory context shows ''any taxes'' limited to taxes of the Republic of Panama); *Mastro Plastics Corp.* v. *NLRB*, 350 U.S. 270–85 (1956) (''any strike'' does not include strike in response to unfair labor practices); *Bell Atlantic Tel. Cos.* v. *FCC*, 131 F.3d 1044, 1047 (D.C. Cir. 1997) (FCC regulation narrowing ''any * * * facilities or services'' that a Bell operating company could offer affirmed when Court notes ''textual analysis is a language game played on a field known as 'context'''). Therefore, we believe the ''broader frame of reference'' adopted by the *Nixon* Court is not an isolated and unsupported view of the law limited to cases raising federalism concerns.

None of the cases cited by the commenters stand for the proposition that a term modified by the word ''any'' invariably must be given its broadest meaning. In *Harrison* and in other cases, the Court found ''no indication whatever'' that Congress intended a narrower or limited construction of statutory term. These cases discuss a different statutory context than the adoption of the definition of ''modification'' in the NSR provisions of the CAA. These cases do not involve a situation in which Congress incorporated into a section of a statute a term that had been used in another section of the statute and which had been given a different meaning under that prior section. While there is no evidence that Congress compelled EPA to replicate its NSPS interpretation of ''any physical change'' in the NSR program, the fact that the words at issue were given a different construction in the NSPS is an indication that the words do not have a unique and, therefore, unambiguous meaning.

The cases cited by the petitioners and the *Nixon* line of cases are not, in fact, opposing and contradictory. Both support looking for indications in the statute that suggest a more limited meaning of the modified term is possible or intended. We believe such indications exist in the NSR context because the modification definition inserted into the NSR provisions by a 1977 technical amendment to the 1977 CAA Amendments cross-referenced the pre-existing term under CAA 111(a)(4).

Implicitly, at least one of the commenters critical of the ERP recognized that a broader frame of reference can apply by arguing that while in *Nixon*, a broad construction of ''any'' would have led to absurd, futile, and farfetched results, the same would not be true for the NSR modification definition. For NSR, according to the commenters, Congress placed a clear limit on what changes must be considered modifications—those that increase emissions.

In the definition of ''modification,'' we believe a view that ''any'' compels a broad construction of the modified terms also has farfetched implications. The same word ''any'' that modifies ''physical change in'' also modifies ''change in the method of operation of.'' The commenters' argument proves too much. The argument would say that exemptions from the definition of modification on any basis other than *de minimis* increases would not be necessary or appropriate, even long accepted ones that limit the scope of ''change in the method of operation.'' As the preamble to the final rule notes, many of these exemptions can result in non-*de minimis* increases in emissions. 68 FR at 61272. To accept the commenter's argument would mean that one word (''change'') that modifies two clauses in a definition compels a broad construction of one modified clause while allowing discretion when it modifies the other clause.

Another commenter picks up on *Nixon*'s reliance on the doctrine of avoiding absurd or futile results and echoes the view that this doctrine would not apply in the context of the modification definition. In this commenter's view, EPA cannot claim that a broad construction of ''any physical change'' would lead to absurd or futile results when we adopted such a broad construction of ''any physical change'' in the past and continue to seek deference for such an interpretation in ongoing enforcement litigation.

We do not claim our prior interpretation is absurd or futile. The Agency claims that the use of the word ''any'' in the statute does not compel only our prior interpretation.

We note that under the NSPS program, we interpreted CAA 111(a)(4) to allow us to exempt ''[m]aintenance, repair, and replacement which the Administrator determines to be routine for a source category.'' 40 CFR 60.14(e)(1). In contrast, under the NSR program, historically we have interpreted the RMRR provision on a case-by-case basis, and we have not followed suit with the NSPS program in determining that the same activities are categorically exempt from RMRR. Thus, a modification that is categorically exempt under the NSPS could be potentially subject to NSR under our historical RMRR interpretation. It would be incongruous to argue that the identical statutory text incorporated into both the NSPS and the NSR provisions ''clearly'' could support only one meaning in the NSR context while it supports a different meaning in the NSPS context. Rather than saying CAA 111(a)(4) is clear but has two distinct meanings, common sense suggests the wording is ambiguous and allows for an expert agency to adopt reasonable interpretations in the context of the programs.

Commenters incorrectly claim that we have recognized all equipment replacements, including ''like-kind''

[7] State and Municipal Petitioners' Emergency Motion for a Stay, *State of New York* v. *EPA*, D.C. Cir. No. 03–1380 and consolidated cases, at 8 fn.14 (citing *Missouri Mun. League* v. *FCC*, 299 F.3d 949, 954 (8th Cir. 2002), *rev'd sub nom. Nixon* v. *Missouri Mun. League*, 541 U.S. 125, 124 S. Ct. 1555 (2004)). A copy of this motion was submitted to the record as a comment on the reconsideration notice.

[8] E.g., *Harrison* v. *PPG Industries*, 446 U.S. 578 (1980); *United States* v. *Gonzales*, 520 U.S. 1 (1997); *Department of HUD* v. *Rucker*, 535 U.S. 125 (2002). A post-*Nixon* addition to this line of cases is *Norfolk Southern Railway Co.* v. *James N. Kirby, Pty Ltd.*, 125 S. Ct. 385 (2004).

replacements, to be ''physical changes'' within the ordinary meaning of the word. While our October 27, 2003, final rule recognized that ''change'' is susceptible to multiple meanings, and outlined many common uses of the word, we did so to illustrate that there is no one, unambiguous, common meaning for the word. That is the essence of ambiguity.

Several commenters agreed with our view that ''any'' should be interpreted within the ''broader frame of reference'' of its statutory context. One commenter argued that *Nixon* undermined much of the logic in *Wisconsin Electric Power Co.* v. *Reilly*, 893 F.2d 901 (7th Cir. 1990) (*WEPCO*). That case contains sweeping language that repeatedly stressed that ''any'' compelled a broad interpretation of ''any physical change.''

As we noted in our October 27, 2003 final rule, we believe that the *WEPCO* Court was correct to determine that the statute does not unambiguously allow all like-kind replacements to avoid NSR, which was the position advanced by WEPCO in that litigation and which is the position advanced in this reconsideration by certain commenters. The Court's conclusion that the statute does not compel the outcome favored by WEPCO leads to a result that is completely consistent with our current view. Additionally, we continue to believe that the activities at issue in *WEPCO* were not RMRR under the rules at issue in that case. Furthermore, we continue to believe that, under the ERP, the equipment replacements at issue in that case would not automatically qualify as being excluded from major NSR. However, we agree with the commenter that *Nixon* calls into question the additional discussion in *WEPCO* that construes ''any'' to compel a broad view of what is a ''physical change.'' In our view, ''any physical change'' is an ambiguous term that can be defined by the Agency through rulemaking.

Focusing on a different portion of the definition of ''modification,'' commenters argue that Congress provided the only acceptable limitation on what physical changes are not subject to NSR as a modification, which is the requirement that the physical change result in an increase in emissions of any pollutant or the emission of any pollutant not previously emitted.[9] Commenters argue that an agency cannot imply an exemption to, or otherwise insert limiting language into, a categorical statutory provision, especially where Congress was specific in how it would allow the language to be limited.

We disagree with the commenters on three grounds. First, the commenters seem to assume the answer to the threshold question—that equipment replacements that meet the ERP criteria are ''physical changes''—in order to say that we are creating an exemption for activity that is presumptively subject to NSR. We believe that there is no such presumption prior to the agency defining the ambiguous term. Second, we believe that the implication of the commenters' argument would mean that several long-accepted exemptions from NSR would no longer be valid were their position adopted. These exemptions from ''any * * * change in the method of operations'' were discussed in our final rule legal basis. Finally, we believe that the commenters' argument would not give meaning to all the words of the definition of modification. The commenters' position reads the ''any physical change or change in the method of operation'' to be so inclusive that essentially the test for a modification becomes whether emissions increase at a source because there always will be some ''change'' to which the increase can be linked. In contrast, the ERP, as part of our overall approach to the definition of modification, gives meaning to both the ''change'' portion as well as the ''emissions increase'' portion of the definition.

To summarize: With respect to existing sources, the purpose of the NSR provisions is simply to require the installation of controls at the appropriate and opportune time. The kind of replacements that automatically fall within the equipment replacement provision established today do not represent such an appropriate and opportune time. Accordingly, and given that it is consistent with the meaning of ''change'' to treat this kind of replacement as not being a ''change,'' we believe excluding them on that basis from the definition of ''modification'' as used in the NSR program is well calculated to serve all of the policies of the NSR provisions of the CAA, and is therefore a legitimate exercise of our discretion under *Chevron, U.S.A. Inc.* v. *NRDC*, 467 U.S. 837 (1984), to construe an ambiguous term. Likewise, we believe this approach is consistent with the holding in the *WEPCO* case, and with some though not all of that case's reasoning.

Finally, one comment argued that EPA's position on the meaning of ''change'' is internally inconsistent. If equipment replacement is not a change, then the comment suggests EPA lacks authority to regulate changes that exceed 20 percent of the replacement cost. If equipment replacement is a change, then the comment suggests that an exemption can only be justified by *de minimis* authority.

We note that establishing bright line criteria in a manner that reduces regulatory cost and provide certainty is a well-recognized and accepted approach to clarifying ambiguous terms in statutes. See *Time Warner Entertainment Co. LP* v. *FCC*, 240 F.3d 1126, 1141 (D.C. Cir. 2001). The ERP simply establishes bright lines for when an equipment replacement activity is automatically excluded from major NSR.

As we explained in our final ERP rule preamble, this approach is consistent with our approach towards ''reconstruction'' in the NSPS context. Under the NSPS rules, we treat a 50 percent threshold as a trigger for scrutiny as to whether the source must meet the NSPS. 40 CFR 60.15(b)(1). We then assess the technological and economic feasibility of meeting the NSPS standard. 40 CFR 60.15(b)(2).

In the ERP, we do not take the position that all like-kind or functionally-equivalent replacements automatically are or are not changes. Instead, we simply draw criteria for when such activities are excluded from NSR and when the multi-factor RMRR approach applies.

c. *Policy objections.* Several comments disputed the manner in which we exercised our discretion in defining which equipment replacement activities are not changes. As noted below, these comments tended to infer that we were defeating Congressional intent through the practical effects of the ERP.

Some commenters criticize the ERP as allowing for perpetual immunity from emissions control requirements. These commenters claim that the ERP reflects EPA's disagreement with Congress's determination that the time to install controls is when a unit is modified. In the commenters' opinion, EPA's belief that it is not plausible that replacements would proceed if emissions controls needed to be installed lacks a factual basis and is contrary to the statutory scheme.

Our disagreement over what constitutes a modification is with the commenter and not Congress. Major source NSR permitting is required unless the source can meet the criteria of the ERP, is not otherwise exempt under the RMRR provision or another NSR exemption or exclusion, and the source does not accept enforceable

[9] We note that it is to these limitations the Alabama Power Court said that we could establish *de minimis* increase levels.

emissions limit below the significant emissions increase levels. When a replacement is a modification under our clearer, more focused definition, NSR permitting will apply, consistent with the Act.

We do not believe, however, the modification provisions of the CAA should be interpreted to ensure that all major facilities either must eventually trigger NSR or must degrade in performance, safety, and reliability. In fact, such an interpretation cannot be squared with the plain language of the CAA. An existing source triggers NSR only if it makes a physical or operational change that results in an emissions increase. Thus, a facility can conceivably continue to operate indefinitely without triggering NSR—making as many physical or operational changes as it desires—as long as the changes do not result in emissions increases. This outcome is an unavoidable consequence of the plain statutory language and is at odds with the notion that Congress intended that every major source would eventually trigger NSR or otherwise fall into disrepair. Moreover, there is nothing in the legislative history of the 1977 Amendments, which created the NSR program, to suggest that Congress intended to force all then-existing sources to go through NSR. To the extent that some members of Congress expressed that view during the debate over the 1990 amendments, such statements are not probative of what Congress meant in 1977. *Central Bank of Denver, N.A.* v. *First Interstate Bank of Denver, N.A.*, 511 U.S. 164, 185—86 (1994), and cases cited.

To the extent that our preamble to the ERP final rule suggested that no replacements ever would take place if controls were required, we recognize that such a generalization is not established by the record, nor was it our intent to make such a sweeping statement. Nevertheless, the substantial body of testimony and studies in the record demonstrates that the vagueness of the RMRR provision operated as a substantial restraint on replacement activity even when such activity would result in safer, more efficient, more reliable processes that had the potential to lower emissions in the overall economy by displacing higher polluting production. See ''New Source Review: Report to the President'', June 2002 (Docket No. OAR–2002–0068, Document No. 0004). Based on the record, we believe that an owner or operator of a source often has the financial incentive to repair existing equipment or artificially constrain production, rather than install emission controls. Therefore, as a general matter, the replacement of that equipment is not, in fact, an opportune time for the installation of such controls. It follows that a policy treating such replacements as an NSR trigger generally will not lead to the installation of controls. Rather, it will merely create incentives to make a plant less productive than its design capacity would allow it to be.

These commenters also claim that Congress intended to strike a different balance between the nation's economic and environmental interests than that which the ERP strikes. They believe requiring emission controls on modified sources would facilitate economic growth and preserve air quality. They point out that the 1977 House Committee report noted, when the emissions impact of each new or modified plant is minimized, ''then more and bigger plants will be able to locate in the same area without serious air quality degradation.''

We agree that we strike the balance between productive capacity of the nation and the protection of the environment differently than these commenters would. We disagree with the assertion that the balance we struck inappropriately weights either consideration. To the extent that Congress left discretion to anyone in striking such a balance, it is afforded to the Administrator and not to litigants. The record demonstrates that our approach, in concert with other CAA programs, is consistent with preserving clean air resources and improving air quality in areas that are not attaining the NAAQS as well as Congress's intentions written explicitly in Sec. 101(b)(1) to preserve the productive capacity of the nation's population and in Sec. 160(3) to balance economic and environmental concerns.

When balancing the economic and environmental interests of the nation, we have also considered that there are many other systematic air programs that will not merely prevent emission increases from existing sources but even reduce emissions at sources we expect to use the ERP. In fact, the entire state implementation plan (SIP) program under Sec. 110(a) establishes a framework for systematic reduction of emissions from existing sources when such reductions are deemed necessary to meet or maintain the NAAQS. The CAA places primary responsibility on the States to achieve the emissions reductions needed to attain and maintain the NAAQS. Over the years, States have in fact achieved significant emissions reductions in furtherance of this obligation.

To assist States, we have developed model market-based programs patterned after the successful Acid Rain provision in Title IV of the CAA. For example, EPA's recently issued ''Clean Air Interstate Rule (CAIR),'' will ensure, through States adopting a ''cap and trade'' or other program approach, that overall emissions from electric utilities throughout much of the Eastern part of the country will meet overall emission limits that are sharply below that which they emit today. CAIR ensures that, by 2015, SO_2 and NO_X emissions will be permanently reduced by 5.4 million tons and 2.0 million tons, respectively, over 2003 levels. Additional emission reductions will occur after 2015 when CAIR is fully implemented.

There are other CAA programs, as well, that are specifically tailored to require emission reductions from existing utility and nonutility sources. These programs include the Maximum Achievable Control Technology (MACT) standards that apply to new and existing sources of air toxics and Control Technique Guidelines that provide guidance to states in determining Reasonably Available Control Technology (RACT) for sources in ozone nonattainment areas. All of these CAA measures will apply systematically to existing sources, and are unaffected by the applicability or non-applicability of any NSR exclusion, such as the RMRR exclusion and its further definition as set forth in the ERP. And, in appropriate circumstances, a State may seek to use CAA Section 126 to petition for additional controls on out-of-state sources.

Even in the absence of these other CAA programs, we note that the substitution effect of replacing deteriorating emission sources with well-maintained emission sources will generally reduce emissions per unit of output. The ERP itself should not materially affect demand in markets. Thus, to the extent individual sources will increase output (and emissions) following maintenance allowed by the ERP, output (and emissions) at other plants will decrease. Thus, we conclude that the ERP will not lead to an overall emission increase.

In contrast to the CAA programs discussed above that systematically and efficiently obtain emission reductions, the NSR program for existing sources, as that program existed before the ERP, was applied in a scattershot manner, only triggered by ''modifications'' however defined on a case-by-case manner. Under NSR, emissions reductions can only be obtained in a ''catch-as-catch-can'' manner, and there never has been and never can be a date

certain by which all existing sources in an area of the country must comply with an emission cap or a NAAQS. Moreover, as fully explained in our recent brief filed in defense of the NSR Improvements Rule of December 31, 2002, the NSR program is not an emission reduction program. It is a program to limit emission increases resulting from physical and operational changes. Brief for Respondent at 73–75, *State of New York* v. *U.S. EPA,* No. 02–1387 & consolidated cases (D.C. Cir.) (''If Congress had intended to compel decreases in emissions, it would be irrational for the requirement to be triggered only when a facility, in fact, increases its emissions''). In light of the programs under the Act that systematically and efficiently allow for both reductions in emissions and firm caps on emissions, and the scattershot applicability and limited goals of NSR program with respect to existing sources, it was appropriate for us to strike the balance of economic and environmental interests in accordance with the CAA, as we did when we changed our method for implementing the modification definition in the NSR program.

Commenters suggest that EPA's decision in promulgating the ERP is not entitled to deference because, in their view, it appears that Congress would not have sanctioned an interpretation that allows sources to conduct multi-million dollar refurbishment activities that increase emissions without triggering NSR. However, the record establishes that adoption of the ERP will not cause overall emissions to increase, while, at the same time, safety, efficiency, and reliability of plants will improve. Furthermore, improvements in safety, efficiency, and reliability improve environmental performance by minimizing the frequency of startup, shutdowns, and malfunctions. While the record contains some conflicting data and studies, Congress left the weighing of this information and the forming of policies based on this information to EPA as an expert agency. We considered the quality and validity of the submitted data and studies in developing our conclusions. Our decisions in this matter are entitled to deference under Chevron.

2. The 20 Percent Replacement Cost Threshold

In the December 31, 2002 proposed rule, EPA solicited comments on the ERP approach. At that time, we sought input on a range of possible percentages of cost that could serve as one of the criteria that must be met to qualify for the RMRR exclusion from NSR. We asked for comment on percentages ranging up to 50 percent, the threshold for reconstruction under the New Source Performance Standards (NSPS) program. 67 FR at 80301.

Under the ERP, a project must meet four separate requirements before it is automatically excluded from NSR pursuant to the ERP. The 20 percent replacement cost threshold is but one of the four requirements. Thus, projects that meet the 20 percent threshold are not exempt from major NSR under the ERP if they do not meet the other necessary criteria in the final rule. These other criteria require that the replaced component: (1) Be identical or functionally equivalent; (2) does not alter the basic design parameters of the process unit; and (3) does not cause the process unit to exceed any emission limitation or operational limitation (that has the effect of constraining emissions) that applies to any component of the process unit and that is legally enforceable.

Some commenters have asserted that an equipment replacement project would be excluded from NSR if it costs 20 percent or less of the replacement cost of a process unit. However, a replacement project must meet *all four* of the ERP criteria for the ERP to apply. Thus, only if the replaced component is (1) identical or functionally equivalent, (2) does not alter the basic design parameters of the process unit, and (3) does not cause the unit to exceed any emission or operational limit, will the 20 percent criterion be relevant. Of all of these qualifiers, including the 20 percent cost threshold, the key qualifier is that the equipment replacement is ''like-kind'' (*i.e.*, identical or functionally equivalent). This criterion provides strong support for our determination and conclusion that where the ERP applies, the process unit has undergone ''no change'' as a result of the activity at issue. Thus, the 20 percent cost threshold serves primarily as an administrative threshold, by which activities that fall beneath threshold and which also meet the other rule criteria safeguards qualify automatically as RMRR, while those activities that meet the other criteria but are over the 20 percent cost threshold may still be RMRR, but only by applying the multi-factor RMRR approach.

In the final ERP, we presented policy arguments and data analyses supporting 20 percent of replacement costs of a process unit as the threshold cost that would entitle an equipment replacement activity (or aggregation of activities) to qualify automatically as RMRR, if the other three criteria were met. See 68 FR 61255–61258. In short, we received a substantial amount of industry data—both from electric utilities and from other industry sectors—that supported a decision to set the threshold at 20 percent. These data show that many like-kind replacements occurring at facilities typically cost less than 20 percent of the process unit's value and do not increase emissions. We also conducted case studies on a number of industries, analyzed the costs involved in the *Wisconsin Electric Power Company* v. *Reilly* (''WEPCO'') case (See 893 F.2d 901 (7th Cir. 1990)) and other relevant information, and provided a legal basis as to why 20 percent is a reasonable ERP cost threshold for equipment replacements across all industries. We also stipulated other rule criteria which must be met to qualify for the ERP. The ERP allows sources to know, with certainty, that RMRR can be conducted without delay in situations where the 20 percent replacement cost criterion and other specified criteria are met.

Petitioners asked EPA to reconsider the 20 percent cost threshold, and claimed that none of EPA's arguments supporting the threshold had appeared in the proposed rule. We granted reconsideration on this issue and solicited additional comment on the data, our analyses, and the policy considerations supporting the 20 percent threshold. We also invited comment on whether it is appropriate to consider approaches used by local governments in determining construction building code applicability when establishing criteria for RMRR determinations.

Thus, our goal in selecting the cost threshold is *not* to create a bright line below which any activity is excluded solely based on its cost. Rather, the threshold is intended to operate in combination with the three other ERP criteria as a screen for determining when the multi-factor RMRR approach is applicable and when it is appropriate to automatically exclude an activity as RMRR based on satisfying the three non-cost ERP criteria. As discussed below, we continue to believe that 20 percent is an appropriate threshold for this purpose. The available data indicate that the 20 percent threshold will effectively identify those more significant projects for which applying the multi-factor RMRR approach is prudent.

Another important factor of the ERP is that related activities must be aggregated in the same way as they would have to be aggregated for other NSR applicability purposes. Under our current policy of aggregation, two or more replacement activities that occur

at different times are not automatically considered separate activities solely because they happen at different times. In the case of replacing an entire facility, it is not feasible that an owner or operator could successfully argue that multiple projects occurring one after the other are not related to one another and should not be aggregated for applicability purposes. These other rule criteria play an important part in determining what replacements can qualify for the ERP.

Much of the comment on the 20 percent replacement value threshold focused on our use of six non-utility case studies that we believe support our selection of a 20 percent replacement value threshold. Though equipment replacement activities vary widely across industry sectors, the six industry sector studies (pulp and paper mills, automobile manufacturing, natural gas transmission, carbon black manufacturing, pharmaceutical manufacturing, and petroleum refining) indicated that equipment replacement activities of the type allowed under the ERP generally do not cause increases in actual emissions. Additionally, though the six studies address specific case examples from only a part of regulated industry, the data indicated that most typical replacement activities fall within the 20 percent threshold, and that some major replacement activities will cross the 20 percent threshold and be subject to the multi-factor RMRR approach.

We received a number of comments through the reconsideration process that were supportive of the calculations performed in the case studies of the six industries. Many of these comments came from the trade groups representing industries that were analyzed in the case studies. These organizations—including the American Forest & Paper Association, Alliance of Automobile Manufacturers, National Petrochemical & Refiners Association, and Interstate Natural Gas Association of America—supported the analyses conducted and conclusions reached in the case studies for each of their industries. In some cases, these trade groups provided further amplification of their cost ranges for projects, which provided additional depth and support to the conclusions of the report. Other commenters stated that the case studies failed to provide sufficient data to support the 20 percent cost threshold.

We never claimed that the case studies encompassed all equipment replacement activities at these industries. Further, we recognize that the case studies do not justify exempting all ''routine'' equipment replacement activity in any one of the case study industries. As discussed elsewhere in this notice, activities falling below the 20 percent replacement value threshold are not exempt under the ERP if they do not meet the other three criteria of the rule. It is important to note that the case studies were performed prior to decisions on the exact form and content of the final rule. If the studies had chosen a different set of assumptions (*e.g.*, for costing of projects, or in defining the process unit), they may have identified additional equipment replacement projects exceeding 20 percent in cost. Furthermore, these studies showed industry-wide results, not plant-specific determinations. Under the ERP, if a plant-specific replacement activity does not satisfy all four of the criteria that must be met to qualify for the RMRR exclusion, then the activity is subject to the multi-factor RMRR approach. The studies indicate that larger, less frequent maintenance activities could exceed the ERP cost threshold and, consequently, would be subject to the multi-factor RMRR approach.[10] Thus, we do not believe there is a basis, nor did the petitioners provide one, that all equipment replacements in these industries would be exempt under a 20 percent cost threshold.

We continue to believe that this information on other industrial sectors beyond electric utilities supports our 20 percent bright line test. In short, the case studies support our view that it is reasonable to assume that equipment replacement activities in the utility industry are similar enough to replacement practices in other industry, such that the 20 percent value determined for utilities is appropriate for industry as a whole.

While most industry commenters agreed that the 20 percent threshold was adequate and reasonable and was well supported by available data, several industry commenters provided additional data as further support that the 20 percent threshold is appropriate. For example, Solar Turbines estimates for their products (turbines of 1 to 14 megawatts in capacity), a periodic refurbishing of the gas producer unit—normally performed every 4 years—would cost 6 to 14 percent of the replacement cost, depending on the extent of deterioration. The Gas Turbine Association noted that the restoration cost as a percentage of total equipment replacement cost varies significantly with turbine unit size. According to the Gas Turbine Association, one supplier estimated a range from 9 percent for a combined cycle system to over 20 percent for a simple cycle system. Other commenters—including the National Petrochemical & Refiners Association and the American Forest & Paper Association—further supported the 20 percent equipment replacement cost threshold providing lists of their plant maintenance activities, many of which were beneath 20 percent in cost, and explained why they felt that their listed projects are routine. We have evaluated the projects described by commenters and, assuming that they would meet all other criteria of the ERP, these projects would not be the types of activities that would be subject to the multi-factor RMRR approach.

We should note, however, that by referring to these lists provided by industry, we are not categorically determining that these activities are RMRR. As we have explained above, the 20 percent threshold is only one part of the ERP. Therefore, each activity must be evaluated against not only the 20 percent cost threshold but also the other three rule criteria before making a determination that these activities are RMRR under the ERP.

Comments filed by the State and Territorial Air Pollution Program Administrators (STAPPA) and the Association of Local Air Pollution Control Officials (ALAPCO) suggested that we reject the percent threshold approach and replace it with a list of RMRR activities, along with a list of projects that are not RMRR, for each major industrial sector. Prior to promulgating the ERP, we evaluated developing a list of activities that are considered RMRR as a component of an overall RMRR program. Although it was decided that we could develop a list for industry sectors for which we had ample amounts of information, we believe that there are too many activities in too many industries, and an excessive number of facility-specific particulars, to effectively improve major NSR implementation by creating such lists. We also were concerned that such lists would need to be updated often.

We believe the ERP provides more clarity than does the multi-factor approach that permitting authorities employed in making past RMRR determinations. With the multi-factor RMRR approach, no ''bright lines'' were ever established, either through rule or guidance, to evaluate the factors (*e.g.*, nature/extent, purpose, frequency and cost), which contributed to regulatory uncertainty. Conversely, to the greatest

[10] As the Alliance of Automobile Manufacturers appointed out in their comment letter, despite the claims of the petitioners, the Abt Study did consider typical replacement project for their industry that exceeded the 20 percent cost threshold.

extent possible, the ERP provides ''bright lines'' by specifying criteria that must be met to qualify as RMRR. Of course, even with the ERP, there will be times when a permitting authority must make judgment calls, such as over whether the process unit's basic design parameters will change as a result of the equipment replacement. However, we believe that the ERP will enable these sorts of decisions to be more limited to engineering judgments and, therefore, less contentious (and more uniform from jurisdiction-to-jurisdiction) than the decisions required under the multi-factor test.

The EPA continues to believe that our basis for selection of the 20 percent replacement cost of the process unit is not arbitrary and capricious, and that there is support in both the rulemaking record and preamble for the 20 percent replacement cost threshold. Considering all of this information, together with the additional supporting data provided by commenters in response to the reconsideration issues, we believe our decision to establish the cost threshold at 20 percent is strongly supported and persuades us that we have established the correct cost threshold for the ERP.

3. Revisions to the Format for Incorporating the PSD FIP Into State Plans

As discussed above, the December 24, 2003 final rule revised the PSD provision in each state plan that lacked an approved state regulation concerning PSD. In lieu of an approved PSD SIP, each of these state plans contained a reference incorporating the relevant provisions of 40 CFR 52.21, the PSD FIP, that applied within the state. Prior to the December 24th rule, we incorporated the relevant paragraphs of 40 CFR 52.21 by referring to the range of paragraphs from the first paragraph incorporated to the last paragraph. This format required updates every time we added paragraphs to section 52.21. The December 24th rule adopted a different cross-referencing format—''40 CFR 52.21 except paragraph (a)(1).'' Under the new format, the cross-references would automatically update whenever new sections were added to the PSD FIP.

We granted reconsideration and solicited comment on the issue of the new format and its ability to automatically update affected state plans whenever EPA modifies the PSD FIP. We did not receive comments in opposition of this new format and thus will not change it. We believe the automatic update function will eliminate paperwork delays and typographical errors associated with future updates to federal PSD requirements. It will reduce the potential for confusion when the PSD rules are updated and will ensure that the relevant federal provisions are included in updated PSD FIPs in a consistent and efficient manner.

B. Remaining Issues in Petitions for Reconsideration

We denied two issues contained in petitioners' requests for reconsideration because they failed to meet the standard for reconsideration under section 307(d)(7)(B) of the CAA. Specifically, on these issues, the petitioners have failed to show: That it was impracticable to raise their objections during the comment period, or that the grounds for their objections arose after the close of the comment period; and/or that their concern is of central relevance to the outcome of the rule. We discuss our reasons for denying reconsideration in the Technical Support Document, which is available on our Web site at *http://www.epa.gov/nsr.* We have concluded that no clarifications to the underlying rules are warranted for these two remaining issues, as described below.

1. Petitioners' Claim That EPA Retroactively Applied the ERP

Petitioners' claimed that EPA retroactively applied the ERP, citing an EPA official's announcement in November 2003 that the Agency would no longer pursue past RMRR violations if the cases had not been filed. In response, we are, and have been, pursuing all filed cases and will continue to file new cases as appropriate. Our decisions on which cases to file is guided by a myriad of factors, including available resources and environmental protection. We acknowledge that the ERP is stayed and not currently effective in any jurisdiction. We continue to request information and put violators on notice when they violate our rules and policies. We note that none of the ERP rule revisions apply to any changes that are the subject of existing enforcement actions that the Agency has brought and none constitute a defense thereto.

As discussed in the final ERP preamble (68 FR 61263), according to the U.S. Supreme Court, an agency may not promulgate retroactive rules absent express congressional authority. See *Bowen* v. *Georgetown Univ. Hosp.,* 488 U.S. 204, 208, 102 L. Ed. 2d 493, 109 S. Ct. 468 (1988). The CAA contains no such expressed grant of authority, and we do not intend by our actions today to create retroactive applicability to the ERP. The promulgated ERP applies only to conduct that occurs after the rule is effective.

2. Petitioners' Claim That EPA Cannot Modify a State's SIP Without a Finding of Deficiency

Petitioners' opposed the provisions in our FIP rule published on December 24, 2003, stating that EPA doesn't have the authority to issue a FIP without a finding of deficiency or notice of such deficiency as required under section 110(k)(5), 42 U.S.C. 7410(k)(5). They noted that, in order to require a State to revise its SIP, the EPA must find that a SIP is ''inadequate to attain or maintain the relevant national ambient air quality standard, to mitigate adequately the interstate pollution described in section 7506a of this title or section 7511c of this title, or to otherwise comply with any requirement of this chapter.'' They further noted that EPA can only require a SIP revision upon the finding that a particular SIP is deficient.

We are not issuing a new FIP. Rather, we are modifying an existing FIP. As such, the original findings of inadequacy of the plans for states subject to the PSD FIP continue to apply because these states never submitted an approvable PSD program in the first place, or have not submitted a revised program since EPA's disapproval of their earlier submission. Our longstanding procedure has been to incorporate § 52.21 into the applicable implementation plan for a state where there is no approved, SIP-based, permitting program. In every PSD rulemaking since the program's inception, we have incorporated all provisions of the promulgated rules into the applicable implementation plan for a state where there is no approved, SIP-based, permitting program. (See 68 FR 11317–11318.) We again are taking these actions in the case of the December 24, 2003 rules.

As a result, we fail to see how the petitioning states were not clearly on notice about our intentions for these portions of the rule. Thus, EPA believes states subject to the PSD FIP had adequate notice and opportunity for comment that EPA planned to amend the FIP citations to § 52.21 to reflect any changes EPA made to § 52.21 in the final NSR rule. Therefore, the petitioners have failed to meet the procedural requirement for reconsideration. Moreover, EPA does not believe it makes sense for states subject to the PSD FIP to have the option to pick what portions of the FIP should apply—these states are free to submit PSD programs for approval as SIP revisions if they wish to apply something other than § 52.21 in its

entirety (although we are making no conclusion about the approvability of a program that does not include all the elements of § 52.21 at this time). Therefore, even if the petitioners had been correct that a procedural error had occurred in this instance, the outcome would not have been of central relevance to the outcome of the rule.

It is inherent in the regulatory nature of a FIP that we retain the authority to make appropriate changes to the Federal Program and that these changes will automatically apply in any jurisdiction in which the Federal FIP applies whether or not we delegate authority to a State to implement the PSD FIP. We believe that the ERP improves the ability of a State to ''attain or maintain the relevant NAAQS, or to mitigate adequately the interstate pollution transport.'' As noted in the preamble to the final ERP (68 FR 61255), nothing in the promulgated ERP would prevent a State or local program from imposing additional requirements necessary to meet Federal, State or local air quality goals.

IV. Statutory and Executive Order Reviews

A. Executive Order 12866—Regulatory Planning and Review

Under Executive Order 12866 (58 FR 51735, October 4, 1993), the Agency must determine whether the regulatory action is ''significant'' and therefore subject to Office of Management and Budget (OMB) review and the requirements of the Executive Order. The Order defines ''significant regulatory action'' as one that is likely to result in a rule that may:

(1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;

(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs, or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

Pursuant to the terms of Executive Order 12866, EPA determined that this rule is a ''significant regulatory action'' within the meaning of the Executive Order. As such, EPA has submitted this action to OMB for review. Changes made in response to OMB suggestions or recommendations will be documented in the public record.

B. Paperwork Reduction Act

The information collection requirements (ICR) for this rule have been prepared under the *Paperwork Reduction Act*, 44 U.S.C. 3501 *et seq.* The EPA has deferred submission of the ICR to Office of Management and Budget (OMB) pending judicial review of the ERP. An ICR document has been prepared by EPA (ICR No. 1230.14), and a copy may be obtained from Susan Auby, U.S. Environmental Protection Agency, Office of Environmental Information, Collection Strategies Division (2822T), 1200 Pennsylvania Avenue, NW., Washington, DC 20460–0001, by e-mail at *auby.susan@epa.gov*, or by calling (202) 566–1672. A copy may also be downloaded off the Internet at *http://www.epa.gov/icr.* The information requirements included in ICR No. 1230.14 are not enforceable until OMB approves them.

The information that ICR No. 1230.14 covers is required for the submittal of a complete permit application for the construction or modification of all major new stationary sources of pollutants in attainment and nonattainment areas, as well as for applicable minor stationary sources of pollutants. This information collection is necessary for the proper performance of EPA's functions, has practical utility, and is not unnecessarily duplicative of information we otherwise can reasonably access. We have reduced, to the extent practicable and appropriate, the burden on persons providing the information to or for EPA. In fact, we feel that this rule will result in less burden on industry and reviewing authorities since it streamlines the process of determining whether a replacement activity is RMRR.

However, according to ICR No. 1230.14, we do anticipate an initial increase in burden for reviewing authorities as a result of the rule changes, to account for revising state implementation plans to incorporate these rule changes. As discussed above, we expect those one-time expenditures to be limited to $580,000 for the estimated 112 affected reviewing authorities. For the number of respondent reviewing authorities, the analysis uses the 112 reviewing authorities count used by other permitting ICR's for the one-time tasks (for example, SIP revisions).

Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purpose of responding to the information collection; adjust existing ways to comply with any previously applicable instructions and requirements; train personnel to respond to a collection of information; search existing data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

An agency 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 OMB control numbers for EPA's regulations in 40 CFR are listed in 40 CFR part 9. When this ICR is approved by OMB, the Agency will publish a technical amendment to 40 CFR part 9 in the **Federal Register** to display the OMB control number for the approved information collection requirements contained in this final rule.

C. Regulatory Flexibility Act

The EPA has determined that it is not necessary to prepare a regulatory flexibility analysis in connection with this final rule.

For purposes of assessing the impacts of today's rule on small entities, small entity is defined as: (1) A small business as defined by the Small Business Administration's regulations at 13 CFR 121.201; (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

After considering the economic impacts of today's final rule on small entities, EPA has concluded that this action will not have a significant economic impact on a substantial number of small entities. In determining whether a rule has a significant economic impact on a substantial number of small entities, the impact of concern is any significant *adverse* economic impact on small entities, since the primary purpose of the regulatory flexibility analyses is to identify and address regulatory alternatives ''which minimize any significant economic impact of the proposed rule on small entities.'' 5 U.S.C. 603 and 604. Thus, an agency may conclude that a rule will not have a significant economic impact on a substantial number of small entities if the rule relieves regulatory burden, or

otherwise has a positive economic effect on all of the small entities subject to the rule.

We believe this final rule will reduce the regulatory burden associated with the major NSR program for all sources, including all small businesses, by improving the operational flexibility of owners and operators, improving the clarity of requirements, and providing alternatives that sources may take advantage of to further improve their operational flexibility. We have therefore concluded that today's final rule will relieve regulatory burden for all affected small entities.

D. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Pub. L. 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector. Under section 202 of the UMRA, EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with ''Federal mandates'' that may result in expenditures to State, local, and tribal governments, in the aggregate, or to the private sector, of $100 million or more in any 1 year. Before promulgating an EPA rule for which a written statement is needed, section 205 of the UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost-effective or least burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows EPA to adopt an alternative other than the least costly, most cost-effective or least burdensome alternative if the Administrator publishes with the final rule an explanation as to why that alternative was not adopted. Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including tribal governments, it must have developed under section 203 of the UMRA a small government agency plan.

The plan must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of EPA regulatory proposals with significant Federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements.

We have determined that today's rule does not contain a Federal mandate that may result in expenditures of $100 million or more for State, local, and tribal governments, in the aggregate, or the private sector in any 1 year. The change in this rule is expected to result in a small decrease in the burden imposed upon reviewing authorities in order for them to be included in the State's SIP, as well as other small increases in burden discussed under ''Paperwork Reduction Act.'' In addition, we believe this final rule will actually reduce the regulatory burden associated with the major NSR program by improving the operational flexibility of owners and operators, and improving the clarity of requirements. Thus, today's action is not subject to the requirements of sections 202 and 205 of the UMRA.

For the same reasons stated above, we have determined that today's action contains no regulatory requirements that might significantly or uniquely affect small governments. Thus, today's action is not subject to the requirements of section 203 of the UMRA.

E. Executive Order 13132—Federalism

Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that 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.''

This final rule does not have federalism implications. It 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, as specified in Executive Order 13132. Thus, Executive Order 13132 does not apply to this rule. Nonetheless, EPA did consult with representatives of state and local governments in developing this rule, through face-to-face consultations and through soliciting comment from State and local officials in our July 1, 2004 **Federal Register** notice.

F. Executive Order 13175—Consultation and Coordination With Indian Tribal Governments

Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000), requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' Today's final action does not have tribal implications as specified in Executive Order 13175. This action will benefit permitting authorities and the regulated community, including any major source owned by a tribal government or located in or near tribal land, by providing increased certainty as to making RMRR determinations within the NSR program. Thus, Executive Order 13175 does not apply to this action.

G. Executive Order 13045—Protection of Children From Environmental Health Risks and Safety Risks

Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997), applies to any rule that: (1) is determined to be ''economically significant'' as defined under Executive Order 12866; and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

Today's action is not subject to the Executive Order because it is not economically significant as defined in Executive Order 12866, and because the Agency does not have reason to believe the environmental health or safety risks addressed by this action present a disproportionate risk to children. We believe that today's action as a whole will result in equal or better environmental protection than provided by earlier regulations, and do so in a more streamlined and effective manner. As a result, today's final rule is not expected to present a disproportionate environmental health or safety risk for children.

H. Executive Order 13211—Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

Today's action is not a ''significant energy action'' as defined in Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001) because it is not likely to have a significant adverse

effect on the supply, distribution, or use of energy.

Today's rule improves the ability of sources to maintain the reliability of production facilities, and effectively utilize and improve existing capacity.

I. National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Pub. L. No. 104–113, 12(d) (15 U.S.C. 272 note) directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical.

Voluntary consensus standards are technical standards (for example, materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. The NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards.

Today's action does not involve technical standards. Therefore, EPA did not consider the use of any voluntary consensus standards.

J. Congressional Review Act

The Congressional Review Act (CRA), 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. Section 808 allows the issuing agency to make a rule effective sooner than otherwise provided by the CRA if the agency makes a good cause finding that notice and public procedure is impracticable, unnecessary or contrary to the public interest. This determination must be supported by a brief statement. 5 U.S.C. 808(2). As stated previously, EPA has made such a good cause finding, including the reasons therefor, and established an effective date of June 10, 2005. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register.** This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

V. Statutory Authority

The statutory authority for this action is provided by sections 101, 111, 114, 116, 301, and 307 of the CAA as amended (42 U.S.C. 7401, 7407, 7411, 7414, 7416, and 7601).

VI. Judicial Review

Under section 307(b)(1) of the Act, the opportunity to file a petition for judicial review of the October 27, 2003 final rule or the December 24, 2003 final rule has passed. Judicial review of today's final action is available only by the filing of a petition for review in the U.S. Court of Appeals for the District of Columbia Circuit by August 9, 2005. Any such judicial review is limited to only those objections that are raised with reasonable specificity in timely comments. Under section 307(b)(2) of the Act, the requirements that are the subject of the October 27, 2003 and December 24, 2003 final rules and today's final action may not be challenged later in civil or criminal proceedings brought by us to enforce these requirements.

List of Subjects in 40 CFR Parts 51 and 52

Environmental protection, Administrative practices and procedures, Air pollution control, Intergovernmental Relations, New source review, Prevention of significant deterioration, Routine maintenance, repair and replacement, Equipment replacement.

Dated: June 6, 2005.

Stephen L. Johnson,

Administrator.

[FR Doc. 05–11546 Filed 6–9–05; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[R03–OAR–2005–PA–0013; FRL–7923–4]

Approval and Promulgation of Air Quality Implementation Plans; Pennsylvania; VOC and NO_X RACT Determinations for Seven Individual Sources

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA proposes to approve revisions to the Commonwealth of Pennsylvania State Implementation Plan (SIP). The revisions were submitted by the Pennsylvania Department of Environmental Protection (PADEP) to establish and require reasonably available control technology (RACT) for seven major sources of volatile organic compounds (VOC) and nitrogen oxides (NO_X) pursuant to the Commonwealth of Pennsylvania's (Pennsylvania or the Commonwealth) SIP-approved generic RACT regulations. EPA is proposing to approve these revisions in accordance with the Clean Air Act (CAA).

DATES: Written comments must be received on or before July 11, 2005.

ADDRESSES: Submit your comments, identified by Regional Material in EDocket (RME) ID Number R03–OAR–2005–PA–0013 by one of the following methods:

Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the on-line instructions for submitting comments.

Agency Web site: *http://www.docket.epa.gov/rmepub/.* RME, EPA's electronic public docket and comment system, is EPA's preferred method for receiving comments. Follow the on-line instructions for submitting comments.

E-mail: *campbell.dave@epa.gov.*

Mail: R03–OAR–2005–PA–0013, David Campbell, Chief, Air Quality Planning Branch, Mailcode 3AP21, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103.

Hand Delivery: At the previously-listed EPA Region III address. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to RME ID No. R03–OAR–2005–PA–0013. EPA's policy is that all comments received will be included in the public docket without change, and may be made available online at *http://www.docket.epa.gov/rmepub/*, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through RME, regulations.gov or e-mail. The EPA RME and the Federal regulations.gov Web sites are an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through RME or regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the

Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the electronic docket are listed in the RME index at *http://www.docket.epa.gov/rmepub/.* Although listed in the index, some information is not publicly available, *i.e.*, CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in RME or in hard copy during normal business hours at the Air Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. Copies of the State submittal are available at the Pennsylvania Department of Environmental Protection, Bureau of Air Quality, PO Box 8468, 400 Market Street, Harrisburg, Pennsylvania 17105.

FOR FURTHER INFORMATION CONTACT: Amy Caprio, (215) 814–2156, or by e-mail at *caprio.amy@epa.gov.*

SUPPLEMENTARY INFORMATION: On January 27, 2005, PADEP submitted revisions to the Pennsylvania SIP. These SIP revisions consist of source-specific operating permits and/or plan approvals issued by PADEP to establish and require RACT for 18 sources pursuant to Pennsylvania's SIP-approved generic RACT regulations. This proposed rulemaking covers the Commonwealth's source-specific RACT determinations for seven of those sources The remaining RACT determinations submitted by PADEP on January 27, 2005 are or will be the subject of separate rulemakings.

I. Background

Pursuant to sections 182(b)(2) and 182(f) of the CAA, Pennsylvania is required to establish and implement RACT for all major VOC and NO_X sources. The major source size is determined by its location, the classification of that area and whether it is located in the ozone transport region (OTR). Under section 184 of the CAA, RACT as specified in sections 182(b)(2) and 182(f) applies throughout the OTR. The entire Commonwealth is located within the OTR. Therefore, RACT is applicable statewide in Pennsylvania.

State implementation plan revisions imposing RACT for three classes of VOC sources are required under section 182(b)(2). The categories are:

(1) All sources covered by a Control Technique Guideline (CTG) document issued between November 15, 1990 and the date of attainment;

(2) All sources covered by a CTG issued prior to November 15, 1990; and

(3) All major non-CTG sources.

The Pennsylvania SIP already has approved RACT regulations and requirements for all sources and source categories covered by the CTGs. The Pennsylvania SIP also has approved regulations to require major sources of NO_X and additional major sources of VOC emissions (not covered by a CTG) to implement RACT. These regulations are commonly termed the ''generic RACT regulations''. A generic RACT regulation is one that does not, itself, specifically define RACT for a source or source categories but instead establishes procedures for imposing case-by-case RACT determinations. The Commonwealth's SIP-approved generic RACT regulations consist of the procedures PADEP uses to establish and impose RACT for subject sources of VOC and NO_X. Pursuant to the SIP-approved generic RACT rules, PADEP imposes RACT on each subject source in an enforceable document, usually a Plan Approval (PA) or Operating Permit (OP). The Commonwealth then submits these PAs and OPs to EPA for approval as source-specific SIP revisions. EPA reviews these SIP revisions to ensure that the Pennsylvania DEP has determined and imposed RACT in accordance with the provisions of the SIP-approved generic RACT rules.

It must be noted that the Commonwealth has adopted and is implementing additional ''post RACT requirements'' to reduce seasonal NO_X emissions in the form of a NO_X cap and trade regulation, 25 Pa Code Chapters 121 and 123, based upon a model rule developed by the States in the OTR. That regulation was approved as SIP revision on June 6, 2000 (65 FR 35842). Pennsylvania has also adopted 25 Pa Code Chapter 145 to satisfy Phase I of the NO_X SIP call. That regulation was approved as a SIP revision on August 21, 2001 (66 FR 43795). Federal approval of a source-specific RACT determination for a major source of NO_X in no way relieves that source from any applicable requirements found in 25 PA Code Chapters 121, 123 and 145.

II. Summary of the SIP Revisions

The following table identifies the sources and the individual plan approvals (PAs) and operating permits (OPs) which are the subject of this rulemaking.

PENNSYLVANIA—VOC AND NO_X RACT DETERMINATIONS FOR INDIVIDUAL SOURCES

Source's name	County	Plan approval (PA #) operating permit (OP #)	Source type	''Major source'' pollutant
Molded Fiber Glass, Union City	Erie	OP 25–035	Spray Booths; Molding Machines	VOC.
SKF, USA, Incorporated	York	67–02010A	Dip Tanks; Spray Tanks	VOC.
Erie Forge and Steel Incorporated	Erie	OP 25–924	Furnaces; Boilers, Preheaters	NO_X.
OSRAM SYLVANIA Products, Inc	Tioga	OP–59–0007	Gas Furnaces; Dryers; Boilers; Hot Water Heaters; Forehearths.	NO_X.
Owens-Brockway Glass Container	Jefferson	OP 33–002	Refiners; Boilers; Furnaces; Forehearths	NO_X.
Texas Eastern Transmission Corporation	Indiana	32–000–230	Turbines; Generators	NO_X.
Johnstown America Corporation	Cambria	11–000–288	Solvent Cleaning; Natural Gas Combustion Sources.	VOC.

Interested parties are advised that copies of Pennsylvania's SIP submittals for these sources, including the actual PAs and OPs imposing RACT, PADEP's evaluation memoranda and the sources' RACT proposals (referenced in PADEP's evaluation memoranda) are included and may be viewed in their entirety in both the electronic and hard copy

versions of the docket for this final rule. As previously stated, all documents in the electronic docket are listed in the RME index at *http://www.docket.epa.gov/rmepub/*. Publicly available docket materials are available either electronically in RME or in hard copy during normal business hours at the Air Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. Copies of the State submittal are available at the Pennsylvania Department of Environmental Protection, Bureau of Air Quality, P.O. Box 8468, 400 Market Street, Harrisburg, Pennsylvania 17105.

EPA is approving these RACT SIP submittals because PADEP established and imposed these RACT requirements in accordance with the criteria set forth in its SIP-approved generic RACT regulations applicable to these sources. In accordance with its SIP-approved generic RACT rule, the Commonwealth has also imposed record-keeping, monitoring, and testing requirements on these sources sufficient to determine compliance with the applicable RACT determinations.

III. Proposed Action

EPA is approving the revisions to the Pennsylvania SIP submitted by PADEP on January 27, 2005 to establish and require VOC and NO_X RACT for seven sources pursuant to the Commonwealth's SIP-approved generic RACT regulations. EPA is soliciting public comments on this proposed rule to approve these source-specific RACT determinations established and imposed by PADEP in accordance with the criteria set forth in its SIP-approved generic RACT regulations applicable to these sources. These comments will be considered before taking final action.

IV. Statutory and Executive Order Reviews

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this proposed action is not a ''significant regulatory action'' and therefore is not subject to review by the Office of Management and Budget. For this reason, this action is also not subject to Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355 (May 22, 2001)). This action merely proposes to approve state law as meeting Federal requirements and imposes no additional requirements beyond those imposed by state law. Accordingly, the Administrator certifies that this proposed 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.*). Because this rule proposes to approve pre-existing requirements under state law and does not impose any additional enforceable duty beyond that required by state law, it does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). This proposed rule also does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), nor will it 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, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999), because it merely proposes to approve a state rule implementing a Federal standard, and does not alter the relationship or the distribution of power and responsibilities established in the Clean Air Act. This proposed rule also is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997), because it is not economically significant. In reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. In this context, in the absence of a prior existing requirement for the State to use voluntary consensus standards (VCS), EPA has no authority to disapprove a SIP submission for failure to use VCS. It would thus be inconsistent with applicable law for EPA, when it reviews a SIP submission, to use VCS in place of a SIP submission that otherwise satisfies the provisions of the Clean Air Act. Thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. As required by section 3 of Executive Order 12988 (61 FR 4729, February 7, 1996), in issuing this proposed rule, EPA has taken the necessary steps to eliminate drafting errors and ambiguity, minimize potential litigation, and provide a clear legal standard for affected conduct. EPA has complied with Executive Order 12630 (53 FR 8859, March 15, 1988) by examining the takings implications of the rule in accordance with the ''Attorney General's Supplemental Guidelines for the Evaluation of Risk and Avoidance of Unanticipated Takings'' issued under the executive order.

This proposed rule to approve source-specific RACT determinations established and imposed by the Commonwealth of Pennsylvania pursuant to its SIP-approved generic RACT regulations does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Nitrogen dioxide, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Authority: 42 U.S.C. 7401 *et seq.*

Dated: June 3, 2005.

Donald S. Welsh,

Regional Administrator, Region III.

[FR Doc. 05–11548 Filed 6–9–05; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 271

[FRL–7922–8]

Louisiana: Final Authorization of State Hazardous Waste Management Program Revision

AGENCY: Environmental Protection Agency (EPA).

ACTION: Immediate final rule.

SUMMARY: Louisiana has applied to the EPA for final authorization of the changes to its hazardous waste program under the Resource Conservation and Recovery Act (RCRA). The EPA has determined that these changes satisfy all requirements needed to qualify for final authorization, and is authorizing the State's changes through this immediate final action. The EPA is publishing this rule to authorize the changes without a prior proposal because we believe this action is not controversial and do not expect comments that oppose it. Unless we receive written comments which oppose this authorization during the comment period, the decision to authorize Louisiana's changes to its hazardous waste program will take effect. If we receive comments that oppose this action, we will publish a document in the **Federal Register** withdrawing this rule before it takes effect, and a separate document in the proposed rules section of this **Federal**

Register will serve as a proposal to authorize the changes.

DATES: This final authorization will become effective on August 9, 2005, unless the EPA receives adverse written comment by July 11, 2005. If the EPA receives such comment, it will publish a timely withdrawal of this immediate final rule in the **Federal Register** and inform the public that this authorization will not take effect.

ADDRESSES: Submit your comments by one of the following methods:

1. Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.
2. E-mail: *patterson.alima@epa.gov*.
3. Mail: Alima Patterson, Region 6, Regional Authorization Coordinator, State/Tribal Oversight Section (6PD–O), Multimedia Planning and Permitting Division, EPA Region 6, 1445 Ross Avenue, Dallas, Texas 75202–2733.
4. Hand Delivery or Courier. Deliver your comments to Alima Patterson, Region 6, Regional Authorization Coordinator, State/Tribal Oversight Section (6PD–O), Multimedia Planning and Permitting Division, EPA Region 6, 1445 Ross Avenue, Dallas Texas 75202–2733.

Instructions: Do not submit information that you consider to be CBI or otherwise protected through regulations.gov, or e-mail. The Federal regulations.gov Web site is an ''anonymous access'' system, which means the EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to the EPA without going through regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, the EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If the EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, the EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

You can view and copy Louisiana's application and associated publicly available materials from 8:30 a.m. to 4 p.m. Monday through Friday at the following locations: Louisiana Department of Environmental Quality, 602 N. Fifth Street, Baton Rouge, Louisiana 70884–2178, phone number (225) 219–3559 and EPA, Region 6, 1445 Ross Avenue, Dallas, Texas 75202–2733, phone number (214) 665–8533. Interested persons wanting to examine these documents should make an appointment with the office at least two weeks in advance.

FOR FURTHER INFORMATION CONTACT: Alima Patterson Region 6 Regional Authorization Coordinator, State/Tribal Oversight Section (6PD–O), Multimedia Planning and Permitting Division, (214) 665–8533, EPA Region 1145 Ross Avenue, Dallas Texas 75202–2733, and e-mail address *patterson.alima@epa.gov*.

SUPPLEMENTARY INFORMATION:

A. Why Are Revisions to State Programs Necessary?

States which have received final authorization from the EPA under RCRA section 3006(b), 42 U.S.C. 6926(b), must maintain a hazardous waste program that is equivalent to, consistent with, and no less stringent than the Federal program. As the Federal program changes, States must change their programs and ask the EPA to authorize the changes. Changes to State programs may be necessary when Federal or State statutory or regulatory authority is modified or when certain other changes occur. Most commonly, States must change their programs because of changes to the EPA's regulations in 40 Code of Federal Regulations (CFR) parts 124, 260 through 266, 268, 270, 273, and 279.

B. What Decisions Have We Made in This Rule?

We conclude that Louisiana's application to revise its authorized program meets all of the statutory and regulatory requirements established by RCRA. Therefore, we grant Louisiana final authorization to operate its hazardous waste program with the changes described in the authorization application. Louisiana has responsibility for permitting treatment, storage, and disposal facilities within its borders (except in Indian Country) and for carrying out the aspects of the RCRA program described in its revised program application, subject to the limitations of the Hazardous and Solid Waste Amendments of 1984 (HSWA). New Federal requirements and prohibitions imposed by Federal regulations that the EPA promulgates under the authority of HSWA take effect in authorized States before they are authorized for the requirements. Thus, the EPA will implement those requirements and prohibitions in Louisiana including issuing permits, until the State is granted authorization to do so.

C. What Is the Effect of Today's Authorization Decision?

The effect of this decision is that a facility in Louisiana subject to RCRA will now have to comply with the authorized State requirements instead of the equivalent Federal requirements in order to comply with RCRA. Louisiana has enforcement responsibilities under its State hazardous waste program for violations of such program, but the EPA retains its authority under RCRA sections 3007, 3008, 3013, and 7003, which include, among others, authority to:

- Do inspections, and require monitoring, tests, analyses, or reports;
- Enforce RCRA requirements and suspend or revoke permits; and
- Take enforcement actions regardless of whether the State has taken its own actions.

This action does not impose additional requirements on the regulated community because the regulations for which Louisiana is being authorized by today's action are already effective under State law, and are not changed by today's action.

D. Why Wasn't There a Proposed Rule Before Today's Rule?

The EPA did not publish a proposal before today's rule because we view this as a routine program change and do not expect comments that oppose this approval. We are providing an opportunity for public comment now. In addition to this rule, in the proposed rules section of today's **Federal Register** we are publishing a separate document that proposes to authorize the State program changes.

E. What Happens if the EPA Receives Comments That Oppose This Action?

If the EPA receives comments that oppose this authorization, we will withdraw this rule by publishing a document in the **Federal Register** before the rule becomes effective. The EPA will base any further decision on the authorization of the State program changes on the proposal mentioned in the previous paragraph. We will then address all public comments in a later final rule. You may not have another opportunity to comment. If you want to comment on this authorization, you must do so at this time. If we receive comments that oppose only the authorization of a particular change to the State hazardous waste program, we will withdraw only that part of this rule, but the authorization of the program

changes that the comments do not oppose will become effective on the date specified above. The **Federal Register** withdrawal document will specify which part of the authorization will become effective, and which part is being withdrawn.

F. For What Has Louisiana Previously Been Authorized?

The State of Louisiana initially received final authorization on February 7, 1985, (50 FR 3348), to implement its base Hazardous Waste Management Program. We granted authorization for changes to their program on November 28, 1989 (54 FR 48889) effective January 29, 1990; August 26, 1991 (56 FR 41958) effective August 26, 1991; November 7, 1994 (59 FR 55368) effective January 23, 1995; December 23, 1994 (59 FR 66200) effective March 8, 1995; there were technical corrections made on January 23, 1995 (60 FR 4380), effective January 23, 1995; and another technical correction was made on April 11, 1995 (60 FR 18360) effective April 11, 1995; October 17, 1995 (60 FR 53704) effective January 2, 1996; March 28, 1996 (61 FR 13777) effective June 11, 1996; December 29, 1997 (62 FR 67572) effective March 16, 1998; October 23, 1998 (63 FR 56830) effective December 22, 1998; August 25, 1999 (64 FR 46302) effective October 25, 1999; September 2, 1999 (64 FR 48099) effective November 1, 1999; February 28, 2000 (65 FR 10411) effective April 28, 2000; January 2, 2001 (66 FR 23) effective March 5, 2001 and December 9, 2003 (68 FR 68526) effective February 9, 2004. On November 4, 2004, Louisiana applied for approval of its program revisions for RCRA Cluster XIII including Conditionally Exempt Small Quantity Generator's (CSQGs), Small Quantity Generators (SQGs) and Manifest Requirements. In this application, Louisiana is seeking approval of RCRA Cluster XIII also including Conditionally Exempt Small Quantity Generator's (CSQGs), Small Quantity Generators (SQGs) and Manifest Requirements that was repealed in accordance with 40 CFR 271.21(b)(3).

Since 1979, the State of Louisiana, through the Louisiana Department of Natural Resources, has conducted a program designed to regulate those who generate, transport, treat, store, dispose of or recycle hazardous waste. During the 1983 Regular Session of the Louisiana Legislature, Act 97, the Environmental Affairs Act, was adopted. This Act amended and reenacted Louisiana Revised Statutes (LRS) 30:1051 *et seq.* and also created the Louisiana Department of Environmental Quality (LDEQ). During the 1999 Regular Session of Louisiana Legislature, Act 303 revised the LRS 30:2011 *et seq.*, allowing LDEQ to re-engineer itself to perform more efficiently and to meet its strategic goals.

Act 97, which amended and reenacted Louisiana Revised Statutes 30:1051 et seq; transferred the duties and previously delegated responsibilities of the Department of Natural Resources, Office of Environmental Affairs, to LDEQ. The LDEQ and the Department of Natural Resources, Office of Conservation, has a memorandum of understanding that outlines the protocol for activities associated with the exploration, development, or production of oil, gas, or geothermal resources. The LDEQ has lead agency jurisdictional authority for administering the RCRA Subtitle C program in Louisiana. The LDEQ is designated to facilitate communication between the EPA and the State.

The State law governing the generation, transportation, treatment, storage and disposal of hazardous waste can be found in LRS 30:2171–2205. This part may be cited as the ''Louisiana Hazardous Waste Control Law.'' The laws governing hazardous waste should be viewed as part of a larger framework of environmental laws specified in Title 30, Subtitle II Louisiana Revised Statutes. The State of Louisiana adopted the Federal regulations for Cluster XIII promulgated from July 1, 2003 through June 30, 2004, including CSQGs, SQGs, and Manifest requirements dated November 1, 1981, through September 23, 1987 and the State's regulations which became effective January 20, 2001, May 20, 2001 and September 20, 2004.

State Initiated Changes

The State has made amendments to the provisions listed in the table which follows. These amendments correct typographical and/or printing errors, clarify and make the State's regulations more internally consistent. The State's laws and regulations, as amended by these provisions, provide authority which remains equivalent to and no less stringent than the Federal laws and regulations. These State initiated changes are submitted under the requirements of 40 CFR 271.21(a).

CHANGES TO CONDITIONALLY EXEMPT SMALL QUANTITY AND SMALL QUANTITY GENERATORS

State citation	Federal citation	Result of re-promulgated rule (amended/effective date May 20, 2001)
2205.A.1	268.50(A)(1)	Repealed.
Chapter 39	N/A	Repealed.
4105.B.7	N/A	Language deleted.

G. What Changes Are We Authorizing With Today's Action?

On November 4, 2004, Louisiana submitted a final complete program revision application, seeking authorization of their changes in accordance with 40 CFR 271.21. We now make an immediate final decision, subject to receipt of written comments that oppose this action, that Louisiana's hazardous waste program revision satisfies all of the requirements necessary to qualify for Final authorization. Therefore, we grant the State of Louisiana Final authorization for the following changes: The State of Louisiana's program revisions consist of regulations which specifically govern RCRA Cluster XIII including amendment to CSEQ's SQG's and Manifest requirements as documented below:

Description of federal requirement (include checklist #, if relevant)	**Federal Register** date and page (and/or RCRA statutory authority)	Analogous state authority
1. Manifest Requirements: 40 CFR part 262.22, 264.71(a) 3 and 4, 264.71(b). 264.71(d) and 264.72(b).	45 FR 3322, May 19, 1980, as amended at 45 FR 86970–86974, December 31, 1980; 61 FR 16315, April 12, 1996; 45 FR 33221, May 19, 1980, as amended at 50 FR 4514, January 31, 1985; and 49 FR 10500, March 20, 1984.	Louisiana Revised States (LRS) 30: Section 2001 *et seq.*, with specific cites of 2174, 2175, and 2180 as amended 2002, effective 2002; Louisiana Hazardous Waste Regulations (LHWR) Sections 905.A.4 & 5, 905.B.5, 907.D, 1107.C, and 1199. Appendix A, as amended January 20, 2001; effective January 20, 2001.
2. Small Quantity Generators and Conditionally Exempt Small Quantity Generators Requirements.	45 FR 33119, May 19, 1980; 45 FR 78529, November 25, 1980, as amended at 47 FR 36097, August 18, 1982; 48 FR 14294, April 1, 1983; 50 FR 1999, January 14, 1985; 51 FR 40637 November 7, 1986; 48FR 14228 April 1, 1983; 48 FR 30114 June 30, 1983, as amended at 50 FR 28751, July 15, 1985; 51 FR 10174–10176, March 24, 1986; 52 FR 45799 December 1, 1987; 54 FR 9607, March. 7, 1989; 60 FR 33914, June 29, 1995; 45 FR 33119–33221, May 19, 1980, as amended at 48 FR 3982, January 1983; 50 FR 4514, January 31, 1985; 47 FR 1251, January 11, 1982; 52 FR 35898–35899, September 23, 1987; 51 FR 28682, August 8, 1986, as amended at 56 FR 43705 September 4, 1991; 61 FR 16309, April 12, 1996;[45 FR 33151–33221, May 19, 1980; 51 FR 40636, November. 7, 1980; 51 FR 40638, November 7, 1986; 52 FR 21016, June 4, 1987; and 51 FR 40642, November 7, 1986. 52 FR 21016–21017, June 4, 1987;[56 FR 7208, February 21, 1991; 56 FR 32688, July 17, 1991; 60 FR 25542, May 11, 1995, as amended at 64 FR 36488, July 6, 1999; 57 FR 41612, September 10, 1992; 45 FR 33232 May 19, 1980; 51 FR 25479, July 14, 1986, as amended at 53 FR 34087 September 2, 1988; and 45 FR 78529–78541 November 25, 1980.	LRS:30:2001 *et seq.* with specific cites of 2174, 2175, and 2180, as amended 2002, effective 2002, LHWR Sections 105.D.5.a, 108.A-J, 108.G.3.g.4 and 5 is more stringent because the State assess fees based upon notification including mandatory fees for Conditionally exempt small quantity generators; The Federal rule at 40 CFR 261 does not assess any generator fees. Sections 109. Definitions, 303.E1, 305.C.2, 305.C.4, 909.Introduction, 909.Comment, 1101.I, 1107.A.4, 1109.E.7, 1109.E.7.e, 1109.E.7.f, 1109.E.8 & 9, 1111.C.1 & 2, 1111.C.3, 1111.E, 1113.G.1.e, 1113.G.2, 1307.H, 1501.C.1, 2201.I.4, 2205.A.1, 2245.G. & H., 2249.C.3, 3001.C.3, 3017.B. & C., 3801.A., 3801.C., 3801.D, 4003.B.3, 4105.B.3, 4105.B.7, 4105.B.11, 4105.B.12 & 13, 4301.E, 4313.B, 4438, 4901.A, 4901.E & F, 4907.C and 5137.A, as amended January 20, 2001; effective January 20, 2001.
3. Zinc Fertilizers Made From Recycled Hazardous Secondary Materials. (Checklist 200).	67 FR 48393, July 24, 2002	LRS:30:2001 *et seq.* with specific cites of 2174, 2175, and 2180, as amended 2002, effective 2002, LHWR Sections 105.D, 105.D.1.t, 105.D.1.t.i,–ii, 105.D.t.ii.(a)(b), 105.D.1.t.ii(b)(i)–(iii), 105.D.1.t.ii.(c)–(d), 105.D.t.ii.(d), 105.D.1.t.ii.(d)(i)–(iii), 105.D.t.iii, 105.D.1.t.iii.(a)(d), 105.D.1.t.iv–v, 105.D.1.u, 105.D.1.u.i, 105.D.1.u.i.(a)(b), 105.D.1.u.ii, 105.D.1.u.iii, 1.u.iii(a)– (f), 4139.A.2.c & 3, 4139.A.6, 4139.A.3.a–b, 2223.I, as amended April 2004, effective August 20, 2004.
4. Treatment Variance for Radioactively Contaminated Batteries. (Checklist 201).	67 FR 62618, October 7, 2002	LRS:30:2001 *et seq.* with specific cites of 2174, 2175, and 2180, as amended 2002, effective 2002, LHWR Sections 2299 Table 2, as amended April 2004, effective August 20, 2004.
5. Hazardous Air Pollutant Standards for Combustors-Corrections 2 (Checklist 202).	67 FR 77687, December 19, 2002	LRS:30:2001 *et seq.* with specific cites of 2174, 2175, and 2180, as amended 2002, effective 2002, LHWR Sections 529.F, 535.G, 3115.E, and 537.D, as amended April 2004, effective August 20, 2004.

H. Where Are the Revised State Rules Different From the Federal Rules?

We consider the following State requirements to be more stringent than the Federal requirements: At the State of Louisiana regulations LHWR Sections 105.D.5.a, 108.A–J, 108.G.3.g.4 and 5, are more stringent because the State assess fees based on notifications including mandatory fees for Conditionally exempt small quantity generators. The Federal rule regulation at 40 CFR 261 does not assess any generator's fees. There are no broader in scope provisions in this program revisions.

I. Who Handles Permits After the Authorization Takes Effect?

Louisiana will issue permits for all the provisions for which it is authorized and will administer the permits it issues. The EPA will continue to administer any RCRA hazardous waste permits or portions of permits which we issued prior to the effective date of this authorization. We will not issue any more new permits or new portions of permits for the provisions listed in the Table in this document after the effective date of this authorization. The EPA will continue to implement and issue permits for HSWA requirements for which Louisiana is not yet authorized.

J. What Is Codification and Is the EPA Codifying Louisiana's Hazardous Waste Program as Authorized in This Rule?

Codification is the process of placing the State's statutes and regulations that comprise the State's authorized hazardous waste program into the CFR. We do this by referencing the authorized State rules in 40 CFR part 272. We reserve the amendment of 40 CFR part 272, subpart T for this authorization of Louisiana's program changes until a later date. In this

authorization application the EPA is not codifying the rules documented in this **Federal Register** notice.

K. Statutory and Executive Order Reviews

The Office of Management and Budget (OMB) has exempted this action from the requirements of Executive Order 12866 (58 FR 51735, October 4, 1993), and therefore this action is not subject to review by OMB. This action authorizes State requirements for the purpose of RCRA 3006 and imposes no additional requirements beyond those imposed by State law. Accordingly, I certify that this action 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.*). Because this action authorizes preexisting requirements under State law and does not impose any additional enforceable duty beyond that required by State law, it does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). For the same reason, this action also does not significantly or uniquely affect the communities of Tribal governments, as specified by Executive Order 13175 (65 FR 67249, November 9, 2000). This action 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, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999), because it merely authorizes State requirements as part of the State RCRA hazardous waste program without altering the relationship or the distribution of power and responsibilities established by RCRA. This action also is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997), because it is not economically significant and it does not make decisions based on environmental health or safety risks. This rule is not subject to Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355 (May 22, 2001)) because it is not a significant regulatory action under Executive Order 12866.

Under RCRA 3006(b), the EPA grants a State's application for authorization as long as the State meets the criteria required by RCRA. It would thus be inconsistent with applicable law for the EPA, when it reviews a State authorization application, to require the use of any particular voluntary consensus standard in place of another standard that otherwise satisfies the requirements of RCRA. Thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. As required by section 3 of Executive Order 12988 (61 FR 4729, February 7, 1996), in issuing this rule, the EPA has taken the necessary steps to eliminate drafting errors and ambiguity, minimize potential litigation, and provide a clear legal standard for affected conduct. The EPA has complied with Executive Order 12630 (53 FR 8859, March 15, 1988) by examining the takings implications of the rule in accordance with the ''Attorney General's Supplemental Guidelines for the Evaluation of Risk and Avoidance of Unanticipated Takings'' issued under the Executive Order. This rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. The EPA will submit a report containing this document and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2). This action will be effective August 9, 2005.

List of Subjects in 40 CFR Part 271

Environmental protection, Administrative practice and procedure, Confidential business information, Hazardous waste, Hazardous waste transportation, Indian lands, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements.

Authority: This action is issued under the authority of sections 2002(a), 3006, and 7004(b) of the Solid Waste Disposal Act as amended 42 U.S.C. 6912(a), 6926, 6974(b).

Dated: May 13, 2005.

Lawrence E. Starfield,

Acting Regional Administrator, Region 6.

[FR Doc. 05–11469 Filed 6–9–05; 8:45 am]

BILLING CODE 6560–50–P

Proposed Rules

Federal Register
Vol. 70, No. 111
Friday, June 10, 2005

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.

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Parts 301, 305, 318, and 319

[Docket No. 03–077–1]

Treatments for Fruits and Vegetables

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: We are proposing to amend the regulations to revise the approved doses for irradiation treatment of imported fruits and vegetables. This proposal would establish a new minimum generic dose of irradiation for most arthropod plant pests, establish a new minimum generic dose for the fruit fly family, reduce the minimum dose of irradiation for some specific fruit fly species, and add nine pests to the list of pests for which irradiation is an approved treatment. These actions would allow the use of irradiation to neutralize more pests and to neutralize some pests at lower doses. Furthermore, we are proposing to provide for the irradiation of fruits and vegetables moved interstate from Hawaii at the pest-specific irradiation doses that are now approved for imported fruits and vegetables. We are also proposing to provide for the use of irradiation to treat fruits and vegetables moved interstate from Puerto Rico and the U.S. Virgin Islands. These actions would allow irradiation to serve as an alternative to other approved treatments for additional fruits and vegetables moved interstate from Hawaii, Puerto Rico, and the U.S. Virgin Islands. Finally, we are proposing to add irradiation as a treatment for bananas from Hawaii and to add vapor-heat treatment as an optional treatment for sweetpotatoes from Hawaii. These actions would provide an alternative to the currently approved treatments for those commodities while continuing to provide protection against the spread of plant pests from Hawaii into the continental United States.

DATES: We will consider all comments that we receive on or before August 9, 2005.

ADDRESSES: You may submit comments by any of the following methods:

- EDOCKET: Go to *http://www.epa.gov/feddocket* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Once you have entered EDOCKET, click on the ''View Open APHIS Dockets'' link to locate this document.
- Postal Mail/Commercial Delivery: Please send four copies of your comment (an original and three copies) to Docket No. 03–077–1, Regulatory Analysis and Development, PPD, APHIS, Station 3C71, 4700 River Road Unit 118, Riverdale, MD 20737–1238. Please state that your comment refers to Docket No. 03–077–1.
- Federal eRulemaking Portal: Go to *http://www.regulations.gov* and follow the instructions for locating this docket and submitting comments.

Reading Room: You may read any comments that we receive on this docket in our reading room. The reading room is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 690–2817 before coming.

Other Information: You may view APHIS documents published in the **Federal Register** and related information on the Internet at *http://www.aphis.usda.gov/ppd/rad/webrepor.html.*

FOR FURTHER INFORMATION CONTACT: Dr. Inder P. Gadh, Treatment Specialist, Phytosanitary Issues Management, PPQ, APHIS, 4700 River Road Unit 140, Riverdale, MD 20737–1236; (301) 734–6799.

SUPPLEMENTARY INFORMATION:

Background

The phytosanitary treatments regulations contained in 7 CFR part 305 set out standards and schedules for treatments required in 7 CFR parts 301, 318, and 319 for fruits, vegetables, and articles to prevent the introduction or dissemination of plant pests or noxious weeds into or through the United States. Within 7 CFR part 305, the irradiation treatments subpart (§§ 305.31 through 305.34, referred to below as the regulations) sets out standards and minimum doses for irradiation treatment for imported fruits and vegetables and for regulated articles moved interstate from quarantined areas within the United States, along with other requirements for performing irradiation treatments.

We are proposing to make several amendments to the irradiation treatment regulations for imported fruits and vegetables, for fruits and vegetables moved interstate from Hawaii, Puerto Rico, and the U.S. Virgin Islands, and for regulated articles moved interstate from areas quarantined for Mexican fruit fly or Mediterranean fruit fly. We are also proposing to provide for the use of irradiation treatment for bananas moved interstate from Hawaii and to provide for the use of a vapor heat treatment for sweetpotatoes moved interstate from Hawaii. The changes we are proposing are discussed below by topic.

Irradiation Treatment for Imported Fruits and Vegetables

Generic Minimum Irradiation Dose for Most Arthropod Plant Pests

The Animal and Plant Health Inspection Service (APHIS) published a notice of policy titled ''The Application of Irradiation to Phytosanitary Problems'' in the **Federal Register** on May 15, 1996 (61 FR 24433–24439, Docket No. 95–088–1). In that notice, among other things, we stated that we may develop minimum irradiation doses that are generic to a pest group or a commodity. We also stated that APHIS' Plant Protection and Quarantine (PPQ) program will confer with the U.S. Department of Agriculture's (USDA) Agricultural Research Service (ARS) concerning the adequacy of treatment data, research protocols, and treatment design and that ARS will identify or concur with the minimum dose for efficacy at the level defined by PPQ as providing quarantine security for a pest or complex of pests.

Currently, the regulations for irradiation of imported fruits and vegetables specify minimum doses for 11 fruit flies and the mango seed weevil. The doses required range from 150 gray

to 300 gray. The fact that the required irradiation doses are specific to plant pests rather than the commodities they are associated with reflects the fact that the effectiveness of irradiation treatment is dependent entirely on the dose that is absorbed by the commodity. Specific characteristics of the fruits or vegetables being treated, which may need to be considered in developing other phytosanitary treatments, are irrelevant to the effectiveness of irradiation as long as the required minimum dose is absorbed.

This approach provides importers who must treat fruits and vegetables for plant pests prior to their entry into the United States with some flexibility: As long as the only pests for which a commodity is required by the fruits and vegetables subpart of 7 CFR part 319 (§§ 319.56 through 319.56–8) to be treated or be subject to a systems approach prior to importation into the United States are pests for which irradiation is an approved treatment, then that commodity may be imported into the United States after it undergoes irradiation in accordance with § 305.31, with no need for additional rulemaking. However, it is not uncommon that multiple plant pests of quarantine concern are associated with a fruit or vegetable approved for importation into the United States; irradiation may be currently listed as an approved treatment for only some of these plant pests. In such cases, the fruit or vegetable must either undergo a different treatment capable of neutralizing all the pests or must undergo multiple treatments to neutralize all of those pests.

A generic minimum irradiation dose that is approved to treat a group of plant pests would solve this problem by allowing, in many cases, irradiation to be used as the sole treatment for the pests associated with a particular fruit or vegetable, as long as it could be shown that any quarantine pests identified as being associated with the fruit or vegetable were members of the group of plant pests that were approved for treatment by the generic minimum irradiation dose. Because the generic minimum dose would be approved for a group of plant pests, a pest-specific minimum dose would not have to be approved through the rulemaking process before irradiation could be used to treat the pest or pests of concern associated with a commodity. Thus, such a dose would facilitate international commerce while continuing to provide phytosanitary protection against the group of plant pests that are neutralized by the dose.

In consultation with ARS, PPQ has determined that a dose of 400 gray is sufficient to neutralize all arthropod plant pests other than pupae and adults of the order *Lepidoptera,* for which we lack sufficient information to establish a safe generic dose. Therefore, we are proposing to establish 400 gray as a generic minimum dose for arthropod plant pests except pupae and adults of the order *Lepidoptera.* Irradiation treatment of fruits and vegetables with the proposed minimum dose of 400 gray would have to be conducted in accordance with all the current requirements for dosimetry, packaging, and recordkeeping in § 305.31.

We would not provide for the use of the proposed generic minimum dose to treat mites, mollusks, nematodes, and plant pathogens, none of which are arthropod plant pests, because the irradiation doses necessary to neutralize those plant pests are either not determined or typically much higher than for arthropod plant pests.

ARS and APHIS will continue to review data relating to recommended minimum doses for pupae and adults of the order *Lepidoptera,* and if we determine that these plant pests can be neutralized with the generic dose included in this proposal, we will undertake rulemaking to allow them to be treated with the generic dose. However, as indicated above, sufficient information to establish a generic dose for pupae and adults of the order *Lepidoptera* does not exist at this time.

We believe the proposed generic 400 gray dose for arthropod plant pests, except pupae and adults of the order *Lepidoptera,* would be a conservative requirement given other available evidence on the doses required to neutralize a wide variety of plant pests. The International Plant Protection Convention (IPPC) Guidelines for the Use of Irradiation as a Phytosanitary Measure (ISPM Publication No. 18) lists recommended minimum dose ranges for 8 types of plant pests, excluding mites, mollusks, nematodes, plant pathogens, and pupae and adults of the order *Lepidoptera*; these recommendations were developed based on literature reviews by G.J. Hallman [1] and the research summarized in the International Atomic Energy Agency's International Database on Insect Disinfestation and Sterilization.[2] The proposed 400 gray minimum dose would be equal to the upper bound of the recommended minimum dose range for stored product beetles of the family *Coleoptera*; it would be at least 100 gray higher than the recommended minimum dose ranges for all the other pests for which the generic dose would be an approved treatment. We believe that the proposed generic minimum dose of 400 gray would neutralize the targeted arthropod plant pests effectively.

To accomplish this change, we would add an entry for ''Plant pests of the phylum *Arthropoda* not listed above, except pupae and adults of the order *Lepidoptera*'' to the bottom of the table of approved irradiation doses in § 305.31(a). Because the heading of that table presently reads ''Irradiation for Fruit Flies and Seed Weevils in Imported Fruits and Vegetables,'' we would revise it to read ''Irradiation for Certain Plant Pests in Imported Fruits and Vegetables.'' We would also revise the section heading of § 305.31 to read ''Irradiation treatment of imported fruits and vegetables for certain plant pests.''

We would retain the list of pests for which lower doses of irradiation are an effective treatment in § 305.31(a), so that the generic minimum dose of 400 gray would exist as an option for treating any arthropod plant pest, except pupae and adults of the order *Lepidoptera*, for which irradiation is not approved as a treatment elsewhere in § 305.31(a).

The generic minimum dose would be available as an option for persons wishing to import fruits and vegetables that are affected by arthropod pests, except pupae and adults of the order *Lepidoptera*, that are not listed in the regulations. However, APHIS does not intend to halt research on the doses necessary to neutralize individual pests for which the regulations do not currently prescribe a minimum dose. (For example, in this proposal we are proposing to reduce the minimum doses required to treat several fruit fly species and proposing to add minimum doses to treat nine plant pests for which irradiation has not been approved as a treatment before, as described later in this document.) If the generic minimum dose of 400 gray for most arthropod pests that we are proposing is adopted in a final rule, APHIS will continue to evaluate data on pest irradiation in consultation with ARS and will, if appropriate, undertake rulemaking to add new minimum doses for individual pests to the regulations.

Generic Minimum Dose for Fruit Flies and Minimum Dose Reductions for Individual Fruit Fly Species

Although the generic minimum dose proposed above could be used to treat

[1] See ''Irradiation as a quarantine treatment,'' in *Food Irradiation Principles and Applications,* Molins, R.A. (ed.). New York: J. Wiley & Sons, 2001, p. 113–130, and ''Expanding radiation quarantine treatments beyond fruit flies,'' *Agricultural and Forest Entomology* 2:85–95, 2000.

[2] Available at *http://www-ididas.iaea.org.*

many arthropod plant pests, it is important that required irradiation doses for plant pests be set at the lowest effective level. Higher doses of irradiation treatment cost more to administer, and irradiation causes many fruits and vegetables to undergo changes in color and texture that increase at higher doses.

Accordingly, ARS has undertaken research to determine whether fruit flies currently approved to be treated with irradiation in the regulations can be neutralized at lower doses than are presently required in § 305.31(a), and whether species of fruit flies that are not currently listed in the regulations can be neutralized at a lower dose than the proposed 400 gray generic minimum dose for arthropod pests other than pupae and adults of the order *Lepidoptera.*

This research demonstrated that all fruit flies of the family *Tephritidae* would be neutralized by a dose of 150 gray. Therefore, we are proposing to add the entire family *Tephritidae* to the list of pests for which irradiation is an approved treatment, and to set the required irradiation dose for those fruit flies at 150 gray. This change would reduce the required dose for the Oriental fruit fly (*Bactrocera dorsalis*), for which a 250 gray dose is currently required; the Mediterranean fruit fly (*Ceratitis capitata*), for which a 225 gray dose is currently required; and the melon fly (*Bactrocera curcurbitae*), for which a 210 gray dose is currently required. It would also set a dose for irradiation treatment for any fruit fly not currently listed in § 305.31(a) that is lower than the proposed generic minimum dose of 400 gray for arthropod pests other than pupae and adults of the order *Lepidoptera.*

The research ARS undertook also demonstrated that the proposed 150 gray generic minimum fruit fly dose would be higher than necessary to neutralize certain fruit flies. Specifically, the research found that the Mexican fruit fly (*Anastrepha ludens*) and the Caribbean fruit fly (*Anastrepha suspensa*) are neutralized at 70 gray and that the West Indian fruit fly (*Anastrepha obliqua*), the sapote fruit fly (*Anastrepha serpentina*), the Jarvis fruit fly (*Bactrocera jarvisi*), and the Queensland fruit fly (*Bactrocera tryoni*) are neutralized at 100 gray. Accordingly, we are proposing to allow those fruit flies to be treated at those lower doses rather than at the proposed generic fruit fly minimum of 150 gray.

To accomplish these changes, we would add a new entry to the table in § 305.31(a) for ''Fruit flies of the family *Tephritidae* not listed above'' and set a minimum dose of 150 gray for those fruit flies. We would also revise the minimum doses approved to treat the species mentioned above.

Proposed New Doses for Nine Other Plant Pests

ARS research also indicates that irradiation can be used as a treatment for nine plant pests not currently listed in § 305.31(a). These pests are listed below, along with the irradiation dose at which the ARS research indicates they are neutralized:

Scientific name	Common name	Dose (gray)
Brevipalpus chilensis	False red spider mite	300
Coccus viridis	Green scale	400
Conotrachelus nenuphar	Plum curculio	92
Croptophlebia ombrodelta	Litchi fruit moth	250
Cryptophlebia illepida	Koa seedworm	250
Cylas formicarius elegantulus	Sweetpotato weevil	165
Cydia pomonella	Codling moth	200
Grapholita molesta	Oriental fruit moth	200
Rhagoletis pomonella	Apple maggot	60

We are proposing to add these pests to the table in § 305.31(a), along with the doses of irradiation that are sufficient to neutralize them. Irradiation treatment for these plant pests would be conducted in accordance with the other provisions of § 305.31.

Currently, the regulations in § 319.56–2(k) authorize the use of irradiation as a treatment for imported fruits or vegetables to neutralize ''one or more of the 11 species of fruit flies and one species of seed weevil listed in § 305.31(a).'' To reflect the proposed changes to the pest list in § 305.31(a), we would revise the quoted text to read ''one or more of the plant pests listed in § 305.31(a).'' We would make a similar change to the introductory text of paragraph (a) in § 319.56–2x.

Irradiation Treatment for Fruits and Vegetables Moved Interstate

Pest-Specific Irradiation Doses for Treating Fruits and Vegetables Moved Interstate

The regulations in 7 CFR part 318 prohibit or restrict the interstate movement of fruits, vegetables, and certain other articles from Hawaii, Puerto Rico, the U.S. Virgin Islands, and Guam to prevent the introduction and dissemination of plant pests into the continental United States.

The Hawaiian fruits and vegetables regulations (§§ 318.13 through 318.13–17) prohibit or restrict the interstate movement of fruits and vegetables from Hawaii to prevent the introduction and dissemination of plant pests into the continental United States. Section 318.13–4f of the Hawaiian fruits and vegetables regulations, titled ''Administrative instructions prescribing methods for irradiation treatment of certain fruits and vegetables from Hawaii,'' lists required doses for irradiation treatment for certain fruits and vegetables and sets out facility approval, packaging, and commodity movement requirements.

We are proposing to remove the bulk of § 318.13–4f, because this section is currently duplicated in § 305.34 of the irradiation treatment regulations. In place of current § 318.13–4f, we would set out a single paragraph listing the commodities for which irradiation is an approved treatment and referring the reader to § 305.34 for instructions on how the treatment must be conducted. Because the section heading of § 318.13–4f currently reads ''Administrative instructions prescribing methods for irradiation treatment of certain fruits and vegetables from Hawaii,'' but the methods for irradiation treatment would only be set out in § 305.34, we would amend the section heading to read: ''Irradiation treatment of certain fruits and vegetables from Hawaii.'' (Here and elsewhere, we are proposing to simplify

our section titles by removing references to administrative instructions.)

Because we would remove the substantive treatment provisions from § 318.13–4f and direct readers to § 305.34, we are also proposing to update a reference to movement under a limited permit ''if the provisions of § 318.13–4f are met'' in paragraph (b)(3) of § 318.13–3 to refer to § 305.34. We would make a similar change in the definition of *compliance agreement* in § 318.13–1.

In § 305.34, paragraph (a) lists the Hawaiian commodities for which irradiation is an approved treatment. Unlike the pest-specific required doses in § 305.31 of the irradiation treatment regulations for imported fruits and vegetables, the required doses in § 305.34 are specific to commodities. We have prescribed doses for specific commodities moved interstate from Hawaii, rather than for specific plant pests that are present in Hawaii and that must be neutralized to allow interstate movement, because the minimum doses that we require in our regulations were based on pest risk analyses that were also commodity-specific. The approved irradiation doses for certain fruits and vegetables in the Hawaiian irradiation regulations have been determined to be capable of neutralizing all the pests that might otherwise be introduced to nonquarantined areas of the United States via the interstate movement of these fruits and vegetables.

However, some of the fruits and vegetables for which we receive requests to allow interstate movement from Hawaii are only associated with pests listed in § 305.31(a). Those commodities could be effectively treated according to the pest-specific doses approved for the treatment of imported fruits and vegetables. Accordingly, we are proposing to amend § 305.34 to allow Hawaiian fruits and vegetables to be treated with irradiation for any pests listed in § 305.31(a) at the pest-specific doses listed there and in accordance with the other requirements in § 305.34.

As discussed above, as long as the only pests for which a commodity is required by the fruits and vegetables subpart of 7 CFR part 319 to be treated or be subject to a systems approach prior to importation into the United States are pests for which irradiation is an approved treatment, then that commodity may be imported into the United States after it undergoes irradiation in accordance with § 305.31, with no need for additional rulemaking. Similarly, as long as the only pests for which a commodity is required by the Hawaiian quarantine regulations to be treated or be subject to a systems approach prior to interstate movement are pests for which irradiation is an approved treatment in § 305.31(a), then that commodity would be able to be moved interstate after it undergoes irradiation for those pests at the doses listed in § 305.31(a) and in accordance with the other requirements in § 305.34, with no need for additional rulemaking.

For commodities that are not currently allowed to be moved interstate under the Hawaiian territorial quarantine regulations, PPQ would conduct a risk assessment to determine whether irradiation alone or in combination with other phytosanitary measures can treat all the quarantine pests that might be associated with its interstate movement from Hawaii. If it was determined that irradiation would be an effective treatment for these commodities, they would be added to the list of commodities for which irradiation is an approved treatment in § 305.34(a)(1) through notice-and-comment rulemaking. If it was determined that irradiation in combination with other measures would be an effective treatment for these commodities, the regulations setting out the conditions for the importation of such commodities would refer to the provisions of § 305.34 and, if necessary, the pest-specific irradiation doses listed in § 305.31(a). (For example, we are proposing to allow the interstate movement of bananas from Hawaii that have been inspected for certain pests and treated with irradiation; the proposed regulations would be added to § 318.13–4i but would refer to the Hawaiian irradiation regulations in § 305.34 and the pest-specific irradiation doses in § 305.31(a). This proposed change is discussed in more detail below.)

To accomplish this change, we would redesignate the current text of § 305.34(a) as § 305.34(a)(1) and add a new paragraph (a)(2) that would read: ''Any fruits or vegetables not listed in paragraph (a)(1) of this section that are required by this subpart to be treated or subjected to inspection to control one or more of the plant pests listed in § 305.31(a) of this chapter may instead be treated with irradiation. Fruits and vegetables treated with irradiation for plant pests listed in § 305.31(a) must be irradiated at the doses listed in § 305.31(a), and the irradiation treatment must be conducted in accordance with the other requirements of § 305.34.'' We would also add this text to the list of Hawaiian commodities for which irradiation is an approved treatment in our proposed revision of § 318.13–4f.

This change would also allow Hawaiian fruits and vegetables that are otherwise eligible for interstate movement to be irradiated for plant pests at the doses we have proposed to add to the approved irradiation doses for imported fruits and vegetables in § 305.31(a), including the proposed generic minimum dose of 400 gray for arthropod plant pests other than pupae and adults of the order *Lepidoptera*, the proposed generic dose of 150 gray for all fruit flies, the proposed lower doses for certain fruit flies, and the proposed new doses for nine plant pests.

Minimum Dose Reductions for Fruits and Vegetables Moved Interstate From Hawaii

As previously mentioned, paragraph (a) of § 305.34 lists fruits and vegetables moved interstate from Hawaii for which irradiation is an approved treatment. The pests of concern with regard to the interstate movement of all but two of these fruits and vegetables (the mango and the sweetpotato) are the Mediterranean fruit fly, the melon fly, and the Oriental fruit fly, known collectively as the Trifly complex. To treat the fruits and vegetables affected by the Trifly complex, the regulations presently require a minimum irradiation dose of 250 gray to neutralize these pests.

Research conducted by ARS, as discussed under the heading ''Generic Minimum Dose for Fruit Flies and Minimum Dose Reductions for Individual Fruit Fly Species'' earlier in this document, has determined that the three fruit flies of concern for these commodities are neutralized at a dose of 150 gray.

Therefore, we are proposing to reduce the minimum required dose of irradiation from 250 gray to 150 gray for the Hawaiian fruits and vegetables affected by the Trifly complex: Abiu, atemoya, bell pepper, carambola, eggplant, litchi, longan, papaya, pineapple (other than smooth Cayenne), rambutan, sapodilla, Italian squash, and tomato. This action would make our minimum dose requirements for irradiation treatment of Hawaiian fruits and vegetables moved interstate consistent with our proposed minimum dose requirements for irradiation treatment of imported fruits and vegetables.

Irradiation Treatment for Fruits and Vegetables Moved Interstate From Puerto Rico and the U.S. Virgin Islands

The Puerto Rico and U.S. Virgin Islands fruits and vegetables regulations (§§ 318.58 through 318.58–16) prohibit or restrict the interstate movement of

fruits and vegetables from Puerto Rico and the U.S. Virgin Islands to prevent the introduction and dissemination of plant pests into the continental United States. Currently, these regulations do not provide for the use of irradiation as a treatment for fruits and vegetables moved interstate from these locations. We believe that irradiation for fruits and vegetables from Puerto Rico and the U.S. Virgin Islands can serve as an effective alternative treatment to those treatments currently authorized for fruits and vegetables moved interstate from Puerto Rico and the U.S. Virgin Islands in part 305 if those fruits and vegetables are only associated with pests listed in § 305.31(a) as pests for which irradiation is an approved treatment.

Therefore, we are also proposing to amend § 305.34 to provide for the use of irradiation as a treatment for fruits and vegetables moved interstate from Puerto Rico and the U.S. Virgin Islands as well as from Hawaii. The section heading would be amended to read: ''Irradiation treatment of certain fruits and vegetables from Hawaii, Puerto Rico, and the U.S. Virgin Islands.'' We would make similar changes throughout the section. We would retain the information in § 305.34 that is specific to Hawaiian commodities, such as the list of Hawaiian commodities for which irradiation is an approved treatment in proposed § 305.34(a)(1) and the additional requirements for the issuance of a certificate or limited permit for the interstate movement of litchi and sweetpotato from Hawaii in § 305.34(b)(7).

We are also proposing to add a new § 318.58–4b, ''Irradiation treatment of fruits and vegetables from Puerto Rico and the U.S. Virgin Islands,'' to the Puerto Rico and U.S. Virgin Islands fruits and vegetables regulations. Because no commodity-specific irradiation treatment schedules have been developed for fruits and vegetables from Puerto Rico and the U.S. Virgin Islands, this section would read, in its entirety, ''Any fruits or vegetables from Puerto Rico or the U.S. Virgin Islands that are required by this subpart to be treated or subjected to inspection to control one or more of the plant pests listed in § 305.31(a) may instead be treated with irradiation. Fruits and vegetables treated with irradiation for plant pests listed in § 305.31(a) of this chapter must be irradiated at the doses listed in § 305.31(a), and the irradiation treatment must be conducted in accordance with the other requirements of § 305.34.''

Currently, no irradiation facilities exist in Puerto Rico or the U.S. Virgin Islands, and PPQ has received no requests to approve the construction of irradiation facilities in either territory. However, these proposed changes to the regulations in § 305.34 would give persons moving fruits or vegetables interstate from Puerto Rico or the U.S. Virgin Islands the option of moving the fruits and vegetables under limited permit to an irradiation facility in the continental United States for treatment before the fruits and vegetables enter interstate commerce. If moved interstate in this manner, fruits and vegetables from Puerto Rico and the U.S. Virgin Islands would be treated for plant pests listed in § 305.31(a) in accordance with the required doses listed there and in accordance with the other requirements in § 305.34.

As with Hawaiian commodities, as long as the only pests for which a commodity is required by the Puerto Rico and U.S. Virgin Islands quarantine regulations to be treated or be subject to a systems approach prior to interstate movement are pests for which irradiation is an approved treatment in § 305.31, then that commodity would be able to be moved interstate after it undergoes irradiation for those pests at the doses listed in § 305.31(a) and in accordance with the other requirements in § 305.34, with no need for additional rulemaking. For commodities that are not currently allowed to be moved interstate under the Puerto Rico and U.S. Virgin Islands territorial quarantine regulations, PPQ would conduct a risk assessment to determine whether irradiation alone or in combination with other phytosanitary measures can treat all the quarantine pests that might be associated with its interstate movement from Puerto Rico and the U.S. Virgin Islands. If it was determined that irradiation would be an effective treatment for these commodities, they would be approved for treatment with irradiation through notice-and-comment rulemaking.

Under this proposed rule, fruits and vegetables from Puerto Rico and the U.S. Virgin Islands that are listed in § 305.31(h)(2)(ii) and associated with pests for which irradiation is an approved treatment would be allowed to be irradiated for plant pests at the doses we have proposed to add to the approved irradiation doses for imported fruits and vegetables in § 305.31(a), including the proposed generic minimum dose of 400 gray for arthropod plant pests other than pupae and adults of the order *Lepidoptera*, the proposed generic dose of 150 gray for all fruit flies, the proposed lower doses for certain fruit flies, and the proposed new doses for nine plant pests.

In addition, to reflect all of the proposed changes to irradiation treatment for fruits and vegetables from foreign localities and from Hawaii, Puerto Rico, and the U.S. Virgin Islands, we would revise paragraph § 305.2(h)(1), which currently lists the plant pests associated with imported fruits and vegetables for which irradiation is an approved treatment, to read: ''Treatment of fruits and vegetables from foreign localities by irradiation in accordance with § 305.31 may be substituted for other approved treatments for any of the pests listed in § 305.31(a). Treatment of fruits and vegetables from Hawaii, Puerto Rico, and the U.S. Virgin Islands by irradiation at the minimum doses listed in § 305.31(a) and in accordance with § 305.34 may be substituted for other approved treatments for any of the pests listed in § 305.31(a).''

Irradiation Treatment for Regulated Articles Moved Interstate From Areas Quarantined for Mexican Fruit Fly and Mediterranean Fruit Fly

The Mexican fruit fly regulations contained in §§ 301.64 through 301.64–10 restrict the interstate movement of regulated articles from quarantined areas to prevent the spread of Mexican fruit fly (*Anastrepha ludens*) to noninfested areas of the United States. Similarly, the Mediterranean fruit fly regulations contained in §§ 301.78 through 301.78–10 restrict the interstate movement of regulated articles from quarantined areas to prevent the spread of Mediterranean fruit fly (*Ceratitis capitata*) to noninfested areas of the United States.

Within the Mexican fruit fly regulations and the Mediterranean fruit fly regulations, paragraphs §§ 301.64–10(g) and 301.78–10(c), respectively, set out the conditions under which certain regulated articles may be treated with irradiation in order to prevent the spread of those fruit flies via the interstate movement of those regulated articles. We are proposing to remove the bulk of these paragraphs because their provisions are currently duplicated in part 305; § 305.32 duplicates the irradiation provisions relating to the Mexican fruit fly, while § 305.33 duplicates the irradiation provisions relating to the Mediterranean fruit fly. In place of the detailed provisions currently contained in paragraphs §§ 301.64–10(g) and 301.78–10(c), we would indicate that regulated articles may be treated with irradiation in accordance with the provisions of 7 CFR part 305.

In § 305.32, the required dose for Mexican fruit fly is 150 gray; in

§ 305.33, the required dose for Mediterranean fruit fly is 225 gray. Research conducted by ARS, as discussed under the heading ''Generic Minimum Dose for Fruit Flies and Minimum Dose Reductions for Individual Fruit Fly Species'' earlier in this document, has determined that the Mexican fruit fly is neutralized at a dose of 70 gray, while the Mediterranean fruit fly is part of the family of fruit flies that are neutralized at a dose of 150 gray. Therefore, we are proposing to update the dose requirements for those fruit flies in § 305.31(a).

In order to make the Mexican fruit fly and Mediterranean fruit fly irradiation treatment regulations consistent with the other changes proposed in this document, we are proposing to remove references to specific required doses from §§ 305.32 and 305.33 and instead refer to the doses listed in § 305.31(a). For example, the requirement in paragraph § 305.32(d) that fruits and vegetables treated with irradiation for Mexican fruit fly must receive a minimum absorbed ionizing radiation dose of 150 gray (15 krad) would be replaced with a requirement that such fruits and vegetables must receive the approved dose for Mexican fruit fly listed in § 305.31(a). This change would make the required irradiation doses for regulated articles moved interstate from areas quarantined for Mexican fruit fly and Mediterranean fruit fly consistent with the proposed irradiation doses for those fruit flies with regard to fruits and vegetables that are imported or moved interstate from Hawaii, Puerto Rico, or the U.S. Virgin Islands.

Irradiation and Inspection for Bananas Moved Interstate From Hawaii

The regulations in § 318.13–4i allow green bananas of the cultivars ''Williams,'' ''Valery,'' ''Grand Nain,'' and standard and dwarf ''Brazilian'' may be moved interstate from Hawaii under a systems approach. A systems approach is a combination of overlapping phytosanitary measures that provide quarantine security against plant pests.

We are proposing to add two combinations of irradiation and inspection as treatments for bananas from Hawaii. Specifically, bananas, regardless of cultivar or ripeness, from Hawaii would be eligible for interstate movement if they have been inspected in Hawaii for the banana moth, *Opogona sacchari* (Bojen), and have undergone irradiation treatment with a minimum dose of 400 gray at an approved facility. Bananas from Hawaii would also be eligible for interstate movement if they have been inspected in Hawaii for the banana moth and the green scale, *Coccus viridis* (Green), and have undergone irradiation treatment with a minimum dose of 150 gray at an approved facility. We believe either of these measures, which are discussed in detail in the following paragraphs, would provide the necessary phytosanitary protection to prevent the introduction and dissemination of plant pests into the continental United States.

A 1998 report completed by APHIS on the inspection requirements for green bananas from Hawaii identified five pests of concern that could be spread from Hawaii to the rest of the United States by the interstate movement of bananas. These pests are: The banana moth, the green scale, the Mediterranean fruit fly, the melon fly, and the Oriental fruit fly. Copies of this report may be requested from the person listed under **FOR FURTHER INFORMATION CONTACT**.

Of the five pests identified in the report, we believe the green scale and the banana moth can be detected by visual inspection. The green scale is a surface pest, which means that any infestations of green scale on bananas are readily apparent. Although the banana moth is an internal pest, we believe that it can also be detected by visual inspection; bananas infested with banana moth show numerous external signs of infestation, such as holes in the skin and deformed nipples. For both of these pests, we believe that visual inspection can effectively mitigate the risk of their introduction into other areas in the United States via the interstate movement of bananas from Hawaii.

The Mediterranean fruit fly, the melon fruit fly, and the Oriental fruit fly infest bananas only where injury or some fault has exposed the flesh of the fruit. For the fruit flies, visual inspections would not be an effective means of interception; they must be neutralized by treatment.

As discussed above under the heading ''Generic Minimum Dose for Fruit Flies and Minimum Dose Reductions for Individual Fruit Fly Species,'' ARS research indicates that the fruit flies of concern are neutralized at a dose of 150 gray. As discussed above under the heading ''Proposed New Doses for Nine Other Plant Pests,'' ARS research indicates that the green scale is neutralized at a dose of 400 gray. However, we currently lack information on what irradiation dose would be necessary to neutralize the banana moth.

Therefore, we are proposing to provide two options for the irradiation treatment of bananas from Hawaii: The bananas could either be irradiated at 150 gray, a dose sufficient to neutralize the fruit flies associated with bananas from Hawaii, and inspected for the green scale and the banana moth, or the bananas could be irradiated at 400 gray, a dose sufficient to neutralize both the fruit flies and the green scale, and inspected for the banana moth.

We expect that the combinations of treatment with irradiation and inspection would be effective alternatives to the current systems approach for green bananas of certain cultivars. Furthermore, treatment with irradiation would allow bananas of any ripeness or cultivar to be moved interstate from Hawaii; the current regulations, as noted above, only allow certain cultivars of green bananas to be moved interstate under the systems approach described in § 318.13–4i.

To accomplish this change, we would amend § 318.13–4i, which currently describes the systems approach under which green bananas of certain cultivars may currently be imported into the United States. Specifically, we would add a new paragraph indicating that bananas from Hawaii would be eligible to move interstate if they were irradiated at the doses listed in § 305.31(a) and in accordance with the other requirements in § 305.34 for the fruit flies and the green scale and inspected for the banana moth or if they were irradiated for the fruit flies and inspected for the green scale and the banana moth. We would amend the section heading of § 318.13–4i to reflect the fact that it would no longer concern only green bananas.

We would also indicate in paragraph § 318.13–4i(b) that, to be eligible for a certificate for interstate movement, the bananas would have to be treated and inspected in Hawaii. (For litchi and sweetpotato, the two commodities for which inspection is required for certification in § 305.34(b)(7)(i), the regulations require that the inspection be conducted before the treatment is performed. Hawaiian producers have requested that we allow the bananas to be inspected after irradiation treatment; therefore, we have proposed to allow inspection to be conducted before or after irradiation treatment. If bananas from Hawaii were inspected for the banana moth after undergoing irradiation treatment in Hawaii and found to be infested with the banana moth or the green scale, the bananas would not be eligible for interstate movement. In such a case, the cost of performing the treatment would be borne by the grower, as it normally is.)

In addition, to be eligible for a limited permit for the interstate movement of

untreated bananas from Hawaii for treatment on the mainland United States, bananas from Hawaii would have to be inspected for the relevant pests in Hawaii.

Finally, we would add a sentence to § 318.13–3(b)(3) indicating that untreated bananas from Hawaii may be moved interstate for irradiation treatment on the mainland United States if the provisions of § 318.13–4i(b) are met and if the bananas are accompanied by a limited permit issued by an inspector in accordance with § 318.13–4(c).

Vapor Heat Treatment for Sweetpotatoes Moved Interstate From Hawaii

Within part 318, ''Subpart—Sweetpotatoes'' (§§ 318.30 and 318.30a) quarantines Hawaii, Puerto Rico, and the U.S. Virgin Islands because of the sweetpotato scarabee (*Euscepes postfasciatus* Fairm. [Coleoptera: Cucurlionidae], also known as the West Indian sweetpotato weevil) and the sweetpotato stem borer (*Omphisa anastomosalis* Guen. [Lepidoptera: Crambidae], also known as the sweetpotato vine borer) and restricts the interstate movement of sweetpotatoes (*Ipomoea batatas* Poir.) from those places.

Paragraph (c) of § 318.30 allows sweetpotatoes to be moved interstate from Hawaii only if they have been subjected to fumigation with methyl bromide or irradiated in accordance with § 318.13–4f or if they are being moved by the USDA for scientific or experimental purposes. We are proposing to add a vapor heat treatment, combined with tuber cutting and inspection, for sweetpotatoes moved interstate from Hawaii as an alternative to fumigation with methyl bromide and irradiation.

A pest risk assessment completed by APHIS in 2002 and updated in May 2003 identified five pests of concern that could be spread from Hawaii to the rest of the United States by the interstate movement of sweetpotatoes: The two pests already named in the regulations, the sweetpotato scarabee and the sweetpotato stem borer; the gray pineapple mealybug, *Dysmicoccus neobrevipes* (Homoptera: Pseudococcidae); the ginger weevil, *Elytrotreinus subtruncatus* (Coleoptera: Cucurlionidae); and the Kona coffee root-knot nematode, *Meloidogyne konaensis* (Tylenchida: Heteroderidae). Copies of this risk assessment may be requested from the person listed under **FOR FURTHER INFORMATION CONTACT**.

Two of these pests, the gray pineapple mealybug and the Kona coffee root-knot nematode, are external pests. We believe they can be effectively detected by visual inspection, and we would require such visual inspection as a condition of the interstate movement of sweetpotato from Hawaii. This is consistent with the recommendations of the pest risk assessment.

The other three pests, the ginger weevil, the sweetpotato scarabee, and the sweetpotato stem borer, are internal pests, meaning that visual inspection would not be an effective means to intercept them; thus, they must be neutralized by treatment. We believe that the vapor heat treatment we are proposing to allow, combined with the tuber cutting and visual inspection that we would require, would be an effective alternative to the methyl bromide and irradiation treatments currently prescribed by the regulations to control these pests.

The vapor heat treatment would be required to be performed according to the following schedule:

- Temperature probes would have to be placed in the approximate centers of individual sweetpotato roots.
- The air surrounding the sweetpotato roots would have to be heated. After the temperature of the air surrounding the sweetpotato roots reaches 87.8 °F (31 °C), its temperature would have to be incrementally raised from 87.8 °F (31 °C) to 111.2 °F (44 °C) over a period of 240 minutes.
- Using saturated water vapor at 118.4 °F (48 °C), the core temperature of the individual sweetpotato roots would then have to be raised to 116.6 °F (47 °C).
- After the core temperature of the sweetpotato roots reaches 116.6 °F (47 °C), the core temperature would have to be held at 116.6 °F (47 °C) or higher for 190 minutes.

This vapor heat treatment was developed in Japan to treat sweetpotatoes moved from Okinawa to mainland Japan for the West Indian sweetpotato weevil, the sweetpotato vine borer, and the sweetpotato weevil (*Cylas formicarius elegantulus*). A review by ARS has confirmed that this treatment is effective at neutralizing the West Indian sweetpotato weevil and the sweetpotato vine borer.

There is no research available at this time on the use of this vapor heat treatment to neutralize the ginger weevil, which was named as a pest of concern in APHIS' pest risk assessment. Although the sweetpotato is not a known host of the ginger weevil, it may move with sweetpotatoes as a hitchhiker. However, vapor heat treatment has been used effectively in Japan against other weevils, such as the sweetpotato weevil mentioned above. Additionally, no live pests have ever been found in sweetpotatoes treated according to this vapor heat treatment schedule. For these reasons, we believe that this vapor heat treatment would be effective against the ginger weevil. However, as an additional phytosanitary precaution, we are proposing to require that sweetpotatoes treated according to this vapor heat treatment schedule be sampled, cut, and inspected and found to be free of the ginger weevil before the sweetpotatoes would be allowed to move from the treatment facility to their destination. The sampling, cutting, and inspection for the ginger weevil would not have to be performed at the same time as the inspection for the gray pineapple mealybug and the Kona coffee root-knot nematode, although both inspections would be required to be conducted prior to treatment. However, the sampling, cutting, and inspection for ginger weevil would have to be performed under conditions that would prevent any pests that may emerge from the sampled sweetpotatoes from infesting any other sweetpotatoes intended for interstate movement in accordance with these proposed requirements.

Sweetpotatoes treated according to these requirements would also have to be packaged according to certain requirements including fruit fly-proof cartons, wrapping of entire pallet loads, and identification requirements. Untreated sweetpotatoes moved interstate to the mainland United States for treatment would be required to be shipped in sealed shipping containers. These proposed requirements would ensure that quarantine pests would be prevented from infesting shipments of treated sweetpotatoes and that any quarantine pests that may be present in untreated sweetpotatoes do not enter the environment. The proposed requirements are identical to the packaging requirements in § 305.34 for sweetpotatoes treated using irradiation and moved interstate from Hawaii.

We would allow this treatment to be administered either in Hawaii or at an approved treatment facility in the mainland United States. If the sweetpotatoes were treated in Hawaii, they would move from Hawaii under a certificate for interstate movement; if they were treated in the mainland United States, they would move from Hawaii under limited permit, and they would have to be inspected for the gray pineapple mealybug and the Kona coffee root-knot nematode and sampled, cut, and inspected for ginger weevil prior to interstate movement from Hawaii.

To accomplish this change, we would add a new paragraph (k) to the vapor heat treatment regulations in § 305.24 that would set out the vapor heat treatment schedule for sweetpotatoes moved interstate from Hawaii. We would also add a new section § 318.13–4d to the Hawaiian quarantine regulations to set out the additional conditions that must be fulfilled in order to allow the interstate movement of sweetpotatoes from Hawaii that are treated in accordance with proposed § 305.24(k). Finally, we would add a new paragraph (b)(4) to § 318.13–3, which currently sets out conditions of movement for regulated articles moved interstate from Hawaii, that would indicate that sweetpotatoes could be moved under a limited permit for treatment at an approved treatment facility in the continental United States if they have been prepared in accordance with the conditions of the Hawaiian quarantine regulations.

Removal of the Subpart for Sweetpotatoes and Dispersal of Its Provisions

As mentioned earlier in this document, within part 318, ''Subpart—Sweetpotatoes'' (§§ 318.30 and 318.30a) quarantines Hawaii, Puerto Rico, and the U.S. Virgin Islands because of the sweetpotato scarabee and the sweetpotato stem borer and restricts the interstate movement of sweetpotatoes from those places.

Section 318.30 prohibits the interstate movement of sweetpotatoes from Hawaii unless the sweetpotatoes are fumigated with methyl bromide or irradiated and prohibits the interstate movement of sweetpotatoes from Puerto Rico and the U.S. Virgin Islands unless they are fumigated with methyl bromide. Section 318.30a sets out a systems approach using inspection, washing, grading, and application of insecticide under which sweetpotatoes may be moved interstate from Puerto Rico to certain locations in the mainland United States.

With the exception of sweetpotatoes, cotton, cottonseed, and cottonseed products, and soil, the regulations in part 318 are organized first by locality and then by commodity; *e.g.*, if a person wishes to move tomatoes interstate from Puerto Rico, that person would look in the Puerto Rico and U.S. Virgin Islands quarantine regulations to determine whether tomatoes from Puerto Rico could be moved interstate and, if so, under what conditions they would be allowed to move. We believe that this organization reflects how regulated parties use the Code of Federal Regulations, as persons who wish to move a commodity interstate typically are seeking to move that commodity interstate from a specific location. Therefore, we are proposing to remove ''Subpart—Sweetpotatoes'' from part 318 and to disperse its provisions to the Hawaiian quarantine regulations and the Puerto Rico and U.S. Virgin Islands quarantine regulations.

Because the sweetpotatoes subpart has set out restrictions on the interstate movement of sweetpotatoes from Hawaii and from Puerto Rico and the U.S. Virgin Islands, sweetpotatoes are not listed as regulated articles in either the list of regulated articles from Hawaii in § 318.13–2(b) or the list of regulated articles from Puerto Rico and the U.S. Virgin Islands in § 318.58–2(b). Accordingly, we would add an entry for sweetpotatoes to each of those lists.

In the Hawaiian quarantine regulations, § 318.13–4b authorizes the interstate movement of any fruit listed in paragraph (b) of that section if that fruit is inspected by an inspector and treated for fruit flies in accordance with 7 CFR part 305. The treatment requirements and schedule for fumigating sweetpotatoes with methyl bromide are found in 7 CFR part 305. Accordingly, we are proposing to amend the references to ''eligible fruits'' in that paragraph to read ''eligible fruits and vegetables,'' to amend the reference to ''fruit flies'' to read ''plant pests,'' and to add sweetpotatoes to the list of commodities authorized to move interstate in that paragraph. The other treatment available for Hawaiian sweetpotatoes, irradiation, is already authorized in the Hawaiian quarantine regulations at § 318.13–4f. (As described earlier in this document, we are proposing to replace the requirements currently in § 318.13–4f with a list of Hawaiian commodities for which irradiation is an approved treatment. In addition, we are proposing to add a new treatment schedule and a new section § 318.13–4d to authorize vapor heat treatment as a treatment for sweetpotatoes moved interstate from Hawaii. Neither of these changes would be complicated by our removal of the sweetpotatoes subpart.)

In the Puerto Rico and U.S. Virgin Islands quarantine regulations, § 318.58–4 allows an inspector to issue a certificate for interstate movement for regulated fruits and vegetables after undergoing an approved treatment from 7 CFR part 305 and if the articles are handled after treatment in accordance with all conditions that the inspector requires. Since fumigation with methyl bromide is already listed in 7 CFR part 305 as an approved treatment for sweetpotatoes from Puerto Rico and the U.S. Virgin Islands and the schedule and conditions of the treatment are also already set out in 7 CFR part 305, there is no need to modify the Puerto Rico and U.S. Virgin Islands quarantine regulations to accommodate the removal of § 318.30.

However, § 318.30a, as discussed above, sets out a systems approach using inspection, washing and grading, and application of insecticide under which sweetpotatoes may be moved interstate from Puerto Rico. To preserve this option for persons who wish to move sweetpotatoes interstate from Puerto Rico, we would establish a new section § 318.58–4c with the same requirements as § 318.30a. In transferring this section to the Puerto Rico and U.S. Virgin Islands quarantine regulations, however, we would update the language in § 318.30a and reorganize some of its requirements to make it easier to understand.

We would also make several other editorial changes in the Hawaiian quarantine regulations and the Puerto Rico and U.S. Virgin Islands quarantine regulations to reflect the removal of the sweetpotatoes subpart.

Definition of Inspector

We are also proposing to amend the definitions of *inspector* in the Hawaiian quarantine regulations and the Puerto Rico and U.S. Virgin Islands quarantine regulations to reflect the fact that some inspection responsibilities have been transferred to the Department of Homeland Security's Bureau of Customs and Border Protection.

Executive Order 12866 and Regulatory Flexibility Act

This proposed rule has been reviewed under Executive Order 12866. For this action, the Office of Management and Budget has waived its review under Executive Order 12866.

This proposed rule would make several amendments to the current provisions for the use of irradiation as a treatment for various plant pests, allow the use of irradiation and inspection as a treatment for bananas moved interstate from Hawaii as an alternative to the systems approach currently described in the regulations, and allow the use of a vapor heat treatment for sweetpotatoes moved interstate from Hawaii as an alternative to fumigation with methyl bromide and irradiation. The potential economic impacts of the proposed changes are discussed below.

Irradiation Treatment for Fruits and Vegetables

The regulations in § 305.31 set out standards, minimum doses, and other requirements for performing irradiation treatments on imported fruits and vegetables and set out minimum doses necessary to neutralize 11 fruit flies and the mango seed weevil. This proposed rule would add minimum doses for more pests and lower the minimum doses for others. Specifically, this proposal would establish:

- A minimum generic dose of 400 Gy for all arthropod plant pests other than pupae and adults of the order *Lepidoptera;*
- A minimum generic dose of 150 Gy for all fruit flies of the family *Tephriditae;*
- Lower minimum doses for certain fruit flies; and
- New approved minimum doses for nine plant pests.

This proposed rule would also allow irradiation to serve as an alternative to other approved treatments for additional fruits and vegetables moved interstate from Hawaii, Puerto Rico, and the U.S. Virgin Islands. Fruits and vegetables from Hawaii, Puerto Rico, and the U.S. Virgin Islands that are required to be treated by other means for pests listed in § 305.31(a) prior to interstate movement would be allowed to be moved interstate if they are treated with irradiation at the doses listed in § 305.31(a) and in accordance with the other conditions specified in § 305.34.

At present, § 305.34 only provides for irradiation treatment of fruits and vegetables from Hawaii; however, we have determined that irradiation treatment can be used effectively for commodities from Puerto Rico and the U.S. Virgin Islands if the safeguards in § 305.34 are implemented. Currently, no irradiation facilities exist in Puerto Rico and the U.S. Virgin Islands, and no requests have been received to approve the construction of such facilities. However, the proposed rule would provide for the option of moving the commodities under limited permit to an irradiation facility on the U.S. mainland for treatment prior to entering interstate commerce.

Impact on Small Entities of Proposed Changes in Irradiation Treatment of Fruits and Vegetables

The Regulatory Flexibility Act requires that agencies specifically consider the economic impact of their regulations on small entities. The Small Business Administration (SBA) has established size criteria using the North American Industry Classification System (NAICS) to determine which economic entities meet the definition of a small firm.

Irradiation facilities affected by the proposed rule change would belong to one of the following two NAICS categories: (1) Firms providing irradiation services for the treatment of fruits and vegetables, which would fall within NAICS category 115114, ''Postharvest Crop Activities (except Cotton Ginning)''; or (2) firms providing irradiation services for decontamination or sterilization purposes, which would fall within NAICS category 811219, which includes ''Medical and surgical equipment repair and maintenance services.''

Most treatments of Hawaiian produce are likely to occur at an existing irradiation facility on the island of Hawaii. This facility is used to treat other fruits and vegetables for which irradiation is an approved treatment and can be classified under NAICS category 115114, ''Postharvest Crop Activities (except Cotton Ginning).'' The SBA criteria classify this facility as a small entity, since its annual sales are less than $6 million.

Another firm on the U.S. mainland operates two facilities in Illinois and one facility in New Jersey. Its primary service is to provide irradiation treatment for the sanitation of medical devices on contract. This firm is classified within NAICS category 811219, which includes ''Medical and surgical equipment repair and maintenance services.'' However, since it is part of a larger corporation for which annual receipts may exceed $6 million, this firm is not classified as a small entity under the SBA criteria. Thus, at least one firm that could be affected by the proposed changes is a small entity.

However, irradiation facilities, whether large or small, would benefit from the proposed changes. The range of commodities imported and moved interstate for which irradiation would be an approved treatment would increase. At the same time, dosage levels, and therefore operating costs, would decrease for many commodities. The proposed changes to irradiation doses and proposed provisions allowing the use of pest-specific doses to treat commodities for interstate movement would facilitate the importation of fruits and vegetables and their interstate movement from Hawaii, Puerto Rico, and the U.S. Virgin Islands. For certain pests for which irradiation is already an approved treatment, required irradiation dosages would be lowered to the minimum level necessary. In other instances, irradiation would be newly allowed as an alternative phytosanitary treatment.

The proposed changes would result in lower costs and increased flexibility for importers, gains that could be expected to be at least partly realized by U.S. consumers through lower prices, assuming competitive markets. For some commodities, irradiation may also provide quality advantages over other treatment methods in terms of increased shelf life. Choice of irradiation as a treatment alternative would rest upon its expected net returns relative to other treatment methods.

Because these proposed changes would have the potential to affect the importation or interstate movement of a wide range of commodities, it is difficult to predict exactly what economic effects the proposed changes would have. APHIS welcomes public comment on the possible impacts of these proposed changes. However, while affected irradiation firms, large and small, would be expected to benefit, we do not expect the impacts to be significant.

Irradiation and Inspection for Bananas Moved Interstate From Hawaii

The regulations in § 318.13–4i currently provide that green bananas (*Musa* spp.) of the cultivars ''Williams'', ''Valery'', ''Grand Nain'', and standard dwarf ''Brazilian'' may be moved interstate from Hawaii under a systems approach. At this time, only green bananas of these specified cultivars may be moved.

We are proposing to add two combinations of irradiation and inspection as treatments for bananas from Hawaii. Specifically, bananas, regardless of cultivar or ripeness, from Hawaii would be eligible for interstate movement if they have been inspected in Hawaii for the banana moth, *Opogona sacchari* (Bojen), and have undergone irradiation treatment with a minimum dose of 400 gray at an approved facility. Bananas from Hawaii would also be eligible for interstate movement if they have been inspected in Hawaii for the banana moth and the green scale, *Coccus viridis* (Green), and have undergone irradiation treatment with a minimum dose of 150 gray at an approved facility.

Cost of Irradiation Treatment

The cost of irradiation is estimated at 15 cents per pound.[3] We expect that most bananas moved interstate from Hawaii under this proposed approach would be treated at the existing commercial irradiation facility on the

[3] Source: Hawaii Department of Agriculture.

island of Hawaii. However, the proposed treatment could be performed at the irradiation facilities on the mainland United States as well.

Cost of APHIS Inspection

Monitoring of quarantine treatments conducted during standard business hours (weekdays between 8 a.m. and 4:30 p.m.) on the island of Hawaii comes at no cost to the facility. APHIS charges for the monitoring of treatments conducted before 8 a.m. and after 4:30 p.m. and on weekends at a time-and-a-half rate.

Benefits

The proposed combination of irradiation treatment and inspection would offer an alternative to the current systems approach for green fruit of the specified four banana cultivars, and would allow fruit of any ripeness or cultivar to be moved interstate from Hawaii. The approach described in this proposal can be used to mitigate the pest risk associated with all Hawaiian bananas, regardless of cultivar or ripeness. This would allow banana producers and parties moving bananas interstate greater flexibility in operations, more choices with regard to the types of bananas moved interstate, a greater volume of bananas to ship, and less risk of facing rejections during inspection under the current systems approach and Banana Compliance Agreement.

Growers have been reluctant to ship bananas to U.S. mainland markets under the current regulations because § 318.13–4i(c) of the regulations requires that bananas to be moved interstate be inspected by an inspector and found free of the following defects: Prematurely ripe fingers, fused fingers, or exposed flesh (not including fresh cuts made during the packing process). Bananas moved interstate from Hawaii under this systems approach are required to be free of these defects because they are conducive to fruit fly infestation. However, growers are concerned about the risk of having whole shipments of fruit prohibited from interstate movement as a result of a single fault detected when bananas in a random selection of boxes are inspected. No commercial container shipments of bananas have been made to U.S. mainland markets under the current regulations. Since the combinations of irradiation and inspection that would be required by this proposed rule are sufficient to neutralize fruit flies and other pests of concern, the combination of irradiation and inspection described in this proposed rule would provide the Hawaiian banana industry with an alternative treatment for interstate movement and could open new trade opportunities.

U.S. consumers would benefit from an increased supply of bananas. Growers in Hawaii believe that the U.S. mainland demand for bananas from Hawaii may be equivalent to (if not higher than) the existing demand for Hawaiian papaya. Hawaiian growers moved approximately 12 million pounds of papayas to U.S. mainland markets in 2003.[4] Demand may be especially high for the apple banana variety, which has a higher sugar content and more aromatic flavor than the standard commercial banana varieties currently available in U.S. mainland markets. Consumers would benefit from the availability of this specialty product.

Hawaii accounts for almost all U.S. banana production.[5] In 2002, there were 677 banana farms in Hawaii,[6] and the value of sales amounted to $ 8.6 million.[7] Table 1 summarizes production information for bananas and papayas in Hawaii. The utilized production of bananas amounted to 19.5 million pounds in 2002.

The U.S. imported 7,883 million pounds (3,576 million kg) of fresh bananas in 2003, valued at $959 million.[8] Ecuador, Costa Rica, Guatemala, Colombia, and Honduras accounted for 97 percent of the quantity of imports (table 2). Compared to the 7,883 million pounds of bananas currently imported, Hawaii's total production of 20 million pounds is extremely small, and it is not likely that 100 percent of the State's production would be moved to the mainland United States. Thus, as long as phytosanitary mitigation by means of the approved treatments is maintained, the interstate movement of bananas from Hawaii is unlikely to significantly affect current U.S. trade in fresh bananas.

TABLE 1.—PRODUCTION STATISTICS FOR BANANAS AND PAPAYAS IN HAWAII (2002)

Item	Bananas	Papayas
Bearing acreage (acres)	1,300	1,720
Utilized production (1,000 pounds)	19,500	45,900
Price (per pound)	$0.430	$0.260
Value of utilized production	[1] $8.385	[1] $11.924
Movement to mainland U.S. markets (1,000 pounds)	(2)	12,000

Sources: Hawaii Department of Agriculture (movement statistics) and National Agricultural Statistics Service.
[1] In millions.
[2] None.

TABLE 2.—QUANTITY AND VALUE OF FRESH BANANAS IMPORTED INTO THE UNITED STATES FROM THE FIVE MAJOR EXPORTING COUNTRIES (2003)

Country	Quantity (million kg)	Value (million U.S. dollars)
Ecuador	902	237.8
Costa Rica	901	247.5
Guatemala	868	229.1
Colombia	429	117.7

[4] Source: Hawaii Department of Agriculture.

[5] The Census of Agriculture (2002) reports minimal acreage in California, Florida, and Texas, which together account for only 131 acres.

[6] National Agricultural Statistics Service, 2002 Census of Agriculture.

[7] From *http://www.nass.usda.gov/hi/fruit/annban.htm.* Sales of Hawaiian bananas in 2003 were valued at $9.225 million.

[8] World Trade Atlas, 2003.

TABLE 2.—QUANTITY AND VALUE OF FRESH BANANAS IMPORTED INTO THE UNITED STATES FROM THE FIVE MAJOR EXPORTING COUNTRIES (2003)—Continued

Country	Quantity (million kg)	Value (million U.S. dollars)
Honduras	388	100.4
Total imports	3,576	959.3

Source: World Trade Atlas (2003).

Impact on Small Entities of Proposed Irradiation and Inspection for Bananas Moved Interstate From Hawaii

Most treatments of Hawaiian bananas are likely to occur at the existing irradiation facility on the island of Hawaii, which, as noted previously, is considered a small entity.

Banana farming is classified under NAICS category 111339 as ''Other Noncitrus Fruit Farming.'' The SBA considers entities in this category to be small if their average annual receipts are less than $750,000. The 677 banana farms in Hawaii accounted for annual sales of $8.6 million in total in 2002. Therefore, it is likely that most Hawaiian banana farms would be classified as small entities under the SBA criteria. The treatment monitoring program will be mainly operated by APHIS personnel, and no impact is anticipated on other small entities and government agencies.

Vapor Heat Treatment for Sweetpotatoes Moved Interstate From Hawaii

We are proposing to allow vapor heat treatment, combined with tuber cutting and visual inspection, to be used as a treatment for sweetpotatoes moved interstate from Hawaii. We believe this treatment would be an effective alternative to the methyl bromide and irradiation treatments currently prescribed by the regulations to control pests of concern.

Cost of Vapor Heat Treatment

Hawaii has three packing plants on the Island of Hawaii that provide vapor heat treatment services. No other vapor heat treatment plants are currently in operation elsewhere in the State. Since APHIS has yet to certify a facility for the treatment of sweetpotato by vapor heat, the costs of treating this crop specifically cannot be determined with certainty at this time. However, one of the packinghouses estimated that vapor heat treatment costs could amount to 2 to 3 cents per pound for the required treatment protocol. This estimate considered the costs of labor, electricity, water, and sewer service. APHIS has traditionally certified vapor heat treatment chambers (for example, for papaya) in the ''fully loaded configuration.'' The costs of treating sweetpotato in smaller batch loads still have to be determined. This estimate of treatment cost also does not include a mark-up for the facility. The mark-up will be determined by the number of plants providing service and the demand for service.

Cost of APHIS Inspection for Vapor Heat Treatment or Irradiation

Monitoring of quarantine treatments conducted during standard business hours (weekdays between 8 a.m. and 4:30 p.m.) on the island of Hawaii comes at no cost to the facility. APHIS charges for the monitoring of treatments conducted before 8 a.m. and after 4:30 p.m. and on weekends at a time-and-a-half rate.

Comparison of Vapor Heat Treatment, Irradiation, and Methyl Bromide

Vapor heat treatment would provide the Hawaiian sweetpotato industry with an alternative treatment to irradiation or methyl bromide fumigation. If vapor heat treatment could be performed at 2 to 3 cents per pound, it would constitute the most cost-effective treatment, compared to irradiation at 15 cents per pound and fumigation costs ranging from 40.6 cents per pound for 1 pallet to 6.7 cents per pound for 12 pallets (table 3). (These are treatment costs only and do not include the costs of APHIS monitoring or inspection activities or inter-island transportation costs necessary to perform treatments.)

TABLE 3.—ESTIMATED PER-UNIT COST OF VAPOR HEAT TREATMENT, IRRADIATION, AND METHYL BROMIDE FUMIGATION

Treatment	Per unit cost (cents per pound)
Vapor heat treatment	2–3
Irradiation	15
Methyl bromide fumigation: [1]	
One pallet	40.6
Two pallets	20.3

TABLE 3.—ESTIMATED PER-UNIT COST OF VAPOR HEAT TREATMENT, IRRADIATION, AND METHYL BROMIDE FUMIGATION—Continued

Treatment	Per unit cost (cents per pound)
Three pallets	13.5
Four pallets	10.1
Five pallets	8.1
Six pallets	6.7
Nine pallets	7.6
Twelve pallets	6.9

[1] One pallet contains 1,500 pounds of sweetpotatoes.

Sources: Packinghouse estimate (vapor heat treatment); Hawaii Department of Agriculture (irradiation and methyl bromide fumigation).

The availability of vapor heat treatment thus provides the Hawaiian sweetpotato industry with an alternative treatment option at a competitive cost. Furthermore, the vapor heat treatment plants in Hawaii will benefit if sweetpotatoes are included in the list of agricultural products to be treated.

Impact of the Proposal on U.S. Sweetpotato Production

Commercial sweetpotato production in Hawaii occurs on the islands of Hawaii, Kauai, Maui, and Oahu. In 2002, there were 59 sweetpotato farms,[9] and the value of sales was $989,000.[10] The utilized production of sweetpotatoes in Hawaii was 1.8 million pounds in 2001 (table 4). The crop is in year-round production in Hawaii.

TABLE 4.—PRODUCTION STATISTICS FOR HAWAIIAN SWEETPOTATOES (2001)

Item	Amount
Harvested acres	220
Yield per acre (1,000 pounds)	8.2
Production (1,000 pounds)	1,800

[9] National Agricultural Statistics Service, 2002 Census of Agriculture.

[10] From *http://www.nass.usda.gov/hi/vegetble/annveg.htm.*

TABLE 4.—PRODUCTION STATISTICS FOR HAWAIIAN SWEETPOTATOES (2001)—Continued

Item	Amount
Farm price (cents per pound) [1]	50

[1] The 2001 farm price for sweetpotato was 47.3 cents per pound in Hawaii, Honolulu, and the Kauai Counties, and 60 cents per pound in the Maui County (Hawaiian Department of Agriculture).
Source: Hawaii Agricultural Statistics Service.

In the mainland United States, sweetpotato is grown commercially in Alabama, California, Georgia, Louisiana, Mississippi, New Jersey, North Carolina, South Carolina, Texas, and Virginia. North Carolina, Louisiana, Mississippi, and California account for the major proportion of production area by State (table 5). In total, the United States produced 1,355 million pounds of sweetpotatoes from 93,500 acres in 2003 (table 6). The Hawaiian sweetpotato production of 1.8 million pounds thus comprises a minor proportion of the total production of 1,355 million pounds in the United States.

TABLE 5.—ACRES OF SWEETPOTATOES PLANTED IN THE UNITED STATES (2003)

State	Acres planted
North Carolina	42,000
Louisiana	18,000
Missisippi	14,000
California	10,100
Texas	3,400
Alabama	2,900
Others [1]	3,100
Total	93,500

[1] Including Hawaii.
Source: Economic Research Service, USDA.

TABLE 6.—PRODUCTION AND UTILIZATION STATISTICS FOR SWEETPOTATOES IN THE UNITED STATES (2003) [1]

Item	Amount
Acres planted	93,500
Three-year average yield (cwt/acre)	150
Production (million pounds)	1,355
Imports (million pounds)	17.0
Exports (million pounds)	53.0
Total utilization (million pounds) [2]	1,148.3
Per capita use (pounds)	3.9
Three-year average per capita use (pounds)	4.0
Current dollars ($/cwt)	15.75

TABLE 6.—PRODUCTION AND UTILIZATION STATISTICS FOR SWEETPOTATOES IN THE UNITED STATES (2003) [1]—Continued

Item	Amount
Constant 1996 dollars ($/cwt)	13.91

[1] Estimates are for the total United States, and therefore include Hawaii. Forecasted estimates are shown.
[2] Total utilization includes 103 million pounds used for seed and 67.8 million pounds accruing to feed use, shrink, and loss.
Source: Economic Research Service, United States Department of Agriculture. Acres were obtained from Lucier, G. "Sweet potatoes—getting to the root of demand." Economic Research Service, USDA, 2002.

The Hawaiian sweetpotatoes intended for the U.S. mainland markets are of a special purple flesh variety, and they are therefore shipped to the mainland as a specialty product intended for niche markets. U.S. mainland consumers could, therefore, benefit from an increased supply of these specialty sweetpotatoes.

Interstate movement provides Hawaiian growers and shippers with increased marketing opportunities. Sweetpotatoes are in year-round production in Hawaii, but some seasonal variation in volume is expected. Out-shipment to U.S. mainland markets is estimated at 50,000 to 60,000 pounds per week. New plantings of the crop have increased on the island of Hawaii since irradiation was approved as an alternative to methyl bromide fumigation in June 2003. However, plantings are likely to increase each year if the market demand increases for Hawaiian sweetpotatoes regardless of whether the product is treated by methyl bromide fumigation, irradiation, or vapor heat treatment. Nevertheless, even if sweetpotato production increases in Hawaii, the relative volume of production (1.8 million pounds) remains extremely small in comparison to the volume of U.S. mainland sweetpotato production (1.36 billion pounds).

Thus, since Hawaiian production is so small in comparison to U.S. mainland production, and as long as phytosanitary mitigation by the approved treatments is maintained, sweetpotato shipments from Hawaii are unlikely to affect mainland producers. Consumers would benefit from the availability of the purple-fleshed specialty sweetpotato product, and the Hawaiian sweetpotato industry would gain opportunities to expand its mainland U.S. markets.

Impact on Small Entities of Proposed Vapor Heat Treatment of Sweetpotatoes Moved Interstate From Hawaii

The availability of vapor heat treatment at a competitive cost could divert some sweetpotatoes moved interstate from Hawaii from the existing irradiation facility in Hawaii to a vapor heat treatment facility. This would impact the existing irradiation facility in Hawaii, which is a small entity. However, it is not known at this time what proportion of Hawaiian sweetpotatoes moved interstate would be treated with vapor heat instead of irradiation if this proposal becomes effective.

On the other hand, vapor heat treatment facilities could benefit if vapor heat is approved as a treatment for sweetpotatoes moved interstate from Hawaii. However, since facilities for the vapor heat treatment of Hawaiian sweetpotatoes have not been certified yet, the businesses cannot be conclusively categorized into small or large entities at this time.

Sweetpotato farming is classified under NAICS category 111219, ''Other Vegetables (except Potato) and Melon Farming.'' According to the SBA's criteria, an entity involved in crop production is considered small if it has average annual receipts of less than $750,000. The 59 sweetpotato farms in Hawaii accounted for annual sales of $989,000 in total in 2002. Therefore, it is likely that most of these farms would be considered small entities according to the SBA criteria. The monitoring and inspection program will be mainly operated by APHIS personnel, and no impact is anticipated on other small entities and government agencies.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action would not have a significant economic impact on a substantial number of small entities.

Executive Order 12372

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 7 CFR part 3015, subpart V.)

Executive Order 12988

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. If this proposed rule is adopted: (1) All State and local laws and regulations that are inconsistent with this rule will be preempted; (2) no retroactive effect will be given to this

rule; and (3) administrative proceedings will not be required before parties may file suit in court challenging this rule.

Paperwork Reduction Act

In accordance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the information collection or recordkeeping requirements included in this proposed rule have been submitted for approval to the Office of Management and Budget (OMB). Please send written comments to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for APHIS, Washington, DC 20503. Please state that your comments refer to Docket No. 03–077–1. Please send a copy of your comments to: (1) Docket No. 03–077–1, Regulatory Analysis and Development, PPD, APHIS, Station 3C71, 4700 River Road Unit 118, Riverdale, MD 20737–1238, and (2) Clearance Officer, OCIO, USDA, room 404–W, 14th Street and Independence Avenue SW., Washington, DC 20250. A comment to OMB is best assured of having its full effect if OMB receives it within 30 days of publication of this proposed rule.

This proposed rule would revise the approved doses for irradiation treatment of imported fruits and vegetables by establishing a new minimum generic dose of irradiation for most arthropod plant pests, establishing a new minimum generic dose for the fruit fly family, reduce the minimum dose of irradiation for some specific fruit fly species, and adding nine pests to the list of pests for which irradiation is an approved treatment. Furthermore, we are proposing to provide for the irradiation of fruits and vegetables moved interstate from Hawaii at the pest-specific irradiation doses that are now approved for imported fruits and vegetables. We are also proposing to provide for the use of irradiation to treat fruits and vegetables moved interstate from Puerto Rico and the U.S. Virgin Islands. Finally, we are proposing to add irradiation as a treatment for bananas from Hawaii and to add vapor-heat treatment as an optional treatment for sweetpotatoes from Hawaii.

These changes would necessitate the use of certain information collection activities, including the completion of certificates and limited permits for interstate movement of fruits and vegetables and the completion of phytosanitary certificates for imported fruits and vegetables.

We are soliciting comments from the public (as well as affected agencies) concerning our proposed information collection and recordkeeping requirements. These comments will help us:

(1) Evaluate whether the proposed information collection is necessary for the proper performance of our agency's functions, including whether the information will have practical utility;

(2) Evaluate the accuracy of our estimate of the burden of the proposed information collection, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the information collection on those who are to respond (such as through 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).

Estimate of burden: Public reporting burden for this collection of information is estimated to average 0.2487 hours per response.

Respondents: Importers and exporters of fruits and vegetables, irradiation facility personnel, shippers, and State plant regulatory officials.

Estimated annual number of respondents: 17.

Estimated annual number of responses per respondent: 60.2941.

Estimated annual number of responses: 1,025.

Estimated total annual burden on respondents: 255 hours. (Due to averaging, the total annual burden hours may not equal the product of the annual number of responses multiplied by the reporting burden per response.)

Copies of this information collection can be obtained from Mrs. Celeste Sickles, APHIS' Information Collection Coordinator, at (301) 734–7477.

Government Paperwork Elimination Act Compliance

The Animal and Plant Health Inspection Service is committed to compliance with the Government Paperwork Elimination Act (GPEA), which requires Government agencies in general to provide the public the option of submitting information or transacting business electronically to the maximum extent possible. For information pertinent to GPEA compliance related to this proposed rule, please contact Mrs. Celeste Sickles, APHIS' Information Collection Coordinator, at (301) 734–7477.

List of Subjects

7 CFR Part 301

Agricultural commodities, Plant diseases and pests, Quarantine, Reporting and recordkeeping requirements, Transportation.

7 CFR Part 305

Irradiation, Phytosanitary treatment, Plant diseases and pests, Quarantine, Reporting and recordkeeping requirements.

7 CFR Part 318

Cotton, Cottonseeds, Fruits, Guam, Hawaii, Plant diseases and pests, Puerto Rico, Quarantine, Transportation, Vegetables, Virgin Islands.

7 CFR Part 319

Coffee, Cotton, Fruits, Honey, Imports, Logs, Nursery stock, Plant diseases and pests, Quarantine, Reporting and recordkeeping requirements, Rice, Vegetables.

Accordingly, we propose to amend 7 CFR parts 301, 305, 318, and 319 as follows:

PART 301—DOMESTIC QUARANTINE NOTICES

1. The authority citation for part 301 would continue to read as follows:

Authority: 7 U.S.C. 7701–7772; 7 CFR 2.22, 2.80, and 371.3.

Section 301.75–15 also issued under Sec. 204, Title II, Pub. L. 106–113, 113 Stat. 1501A–293; sections 301.75–15 and 301.75–16 also issued under Sec. 203, Title II, Pub. L. 106–224, 114 Stat. 400 (7 U.S.C. 1421 note).

2. In § 301.64–10, paragraph (g) would be revised to read as follows:

§ 301.64–10 Treatments.

* * * * *

(g) *Approved irradiation treatment.* Irradiation, carried out in accordance with the provisions of part 305 of this chapter, is approved as a treatment for any fruit listed as a regulated article in § 301.64–2(a).

3. In § 301.78–10, paragraph (c) would be revised to read as follows:

§ 301.78–10 Treatments.

* * * * *

(c) *Approved irradiation treatment.* Irradiation, carried out in accordance with the provisions of part 305 of this chapter, is approved as a treatment for any berry, fruit, nut, or vegetable listed as a regulated article in § 301.78–2(a) of this subpart.

* * * * *

PART 305—PHYTOSANITARY TREATMENTS

4. The authority citation for part 305 would continue to read as follows:

Authority: 7 U.S.C. 7701–7772; 21 U.S.C. 136 and 136a; 7 CFR 2.22, 2.80, and 371.3.

5. Section 305.2 would be amended as follows:

a. By revising paragraph (h)(1) to read as set forth below.

b. In the table in paragraph (h)(2)(ii), under Hawaii, by adding a new entry, in alphabetical order, for ''banana'' to read as set forth below.

c. In the table in paragraph (h)(2)(ii), under Hawaii, by revising the entry for ''sweetpotato'' to read as set forth below.

§ 305.2 Approved treatments.

* * * * *

(h) *Fruits and vegetables.* (1) Treatment of fruits and vegetables from foreign localities by irradiation in accordance with § 305.31 may be substituted for other approved treatments for any of the pests listed in § 305.31(a). Treatment of fruits and vegetables from Hawaii, Puerto Rico, and the U.S. Virgin Islands by irradiation at the minimum doses listed in § 305.31(a) and in accordance with § 305.34 may be substituted for other approved treatments for any of the pests listed in § 305.31(a).

(2) * * *

(ii) * * *

Location	Commodity	Pest	Treatment schedule
*	*	*	*
Hawaii			
*	*	*	*
	Banana	*Bactrocera curcurbitae, Bactrocera dorsalis, Ceratitis capitata, Coccus viridis.*	IR.
*	*	*	*
	Sweetpotato	*Euscepes postfasciatus, Omphisa anastomosalis, Elytrotreinus subtruncatus.*	MB T101–b–3–1 or § 305.24(k) or IR.
*	*	*	*

* * * * *

6. In § 305.24, a new paragraph (k) would be added to read as set forth below.

§ 305.24 Vapor heat treatment schedules.

* * * * *

(k) *Vapor heat treatment for sweetpotatoes moved interstate from Hawaii.* (1) Temperature probes must be placed in the approximate center of individual sweetpotato roots.

(2) The air surrounding the sweetpotato roots must be heated. After the temperature of the air surrounding the sweetpotato roots reaches 87.8 °F (31 °C), its temperature must be incrementally raised from 87.8 °F (31 °C) to 111.2 °F (44 °C) over a period of 240 minutes.

(3) Using saturated water vapor at 118.4 °F (48 °C), the core temperature of the individual sweetpotato roots must be raised to 116.6 °F (47 °C).

(4) After the core temperature of the sweetpotato roots reaches 116.6 °F (47 °C), the core temperature must then be held at 116.6 °F (47 °C) or higher for 190 minutes.

7. In § 305.31, the section heading and paragraph (a), including the table, would be revised to read as follows:

§ 305.31 *Irradiation treatment of imported fruits and vegetables for certain plant pests.*

(a) *Approved doses.* Irradiation at the following doses for the specified plant pests, carried out in accordance with the provisions of this section, is approved as a treatment for all fruits and vegetables:

IRRADIATION FOR CERTAIN PLANT PESTS IN IMPORTED FRUITS AND VEGETABLES

Scientific name	Common name	Dose (gray)
Anastrepha ludens	Mexican fruit fly	70
Anastrepha obliqua	West Indian fruit fly	100
Anastrepha serpentina	Sapote fruit fly	100
Anastrepha suspensa	Caribbean fruit fly	70
Bactrocera jarvisi	Jarvis fruit fly	100
Bactrocera tryoni	Queensland fruit fly	100
Brevipalpus chilensis	False red spider mite	300
Coccus viridis	Green scale	400
Conotrachelus nenuphar	Plum curculio	92
Croptophlebia ombrodelta	Litchi fruit moth	250
Cryptophlebia illepida	Koa seedworm	250
Cylas formicarius elegantulus	Sweetpotato weevil	165
Cydia pomonella	Codling moth	200
Grapholita molesta	Oriental fruit moth	200
Rhagoletis pomonella	Apple maggot	60
Sternochetus mangiferae (Fabricus)	Mango seed weevil	300
Fruit flies of the family *Tephritidae* not listed above		150
Plant pests of the phylum *Arthropoda* not listed above, except pupae and adults of the order *Lepidoptera*		300

* * * * *

§ 305.32 [Amended]

8. Section 305.32 would be amended as follows:

a. In paragraphs (a)(1) and (d), by removing the words ''a minimum absorbed ionizing radiation dose of 150

Gray (15 krad)'' and adding the words ''the approved dose for Mexican fruit fly listed in § 305.31(a) of this subpart'' in their place.

b. In paragraph (e)(2), by removing the words ''150 Gray (15 krad)'' and adding the words ''the approved dose for Mexican fruit fly listed in § 305.31(a) of this subpart'' in their place.

§ 305.33 [Amended]

9. Section 305.33 would be amended as follows:

a. In paragraphs (a)(1) and (d), by removing the words ''a minimum absorbed ionizing radiation dose of 225 Gray (22.5 krad)'' and adding the words ''the approved dose for Mediterranean fruit fly listed in § 305.31(a) of this subpart'' in their place.

b. In paragraph (e)(2), by removing the words ''225 Gray (22.5 krad)'' and adding the words ''the approved dose for Mediterranean fruit fly listed in § 305.31(a) of this subpart'' in their place.

10. Section 305.34 would be amended as follows:

a. By revising the section heading to read as set forth below.

b. By revising paragraph (a) to read as set forth below.

c. In paragraphs (b), (b)(1), (b)(2)(ii), and (b)(4), by adding the words '', Puerto Rico, or the U.S. Virgin Islands'' after the word ''Hawaii'' each time it occurs.

§ 305.34 Irradiation treatment of certain fruits and vegetables from Hawaii, Puerto Rico, and the U.S. Virgin Islands.

(a) *Approved irradiation treatment.* (1) *Commodity-specific doses.* Irradiation, carried out in accordance with the provisions of this section, is approved as a treatment for the following fruits and vegetables from Hawaii at the specified dose levels:

IRRADIATION FOR PLANT PESTS IN HAWAIIAN FRUITS AND VEGETABLES

Commodity	Dose (gray)
Abiu	150
Atemoya	150
Bell pepper	150
Carambola	150
Eggplant	150
Litchi	150
Longan	150
Mango	300
Papaya	150
Pineapple (other than smooth Cayenne)	150
Rambutan	150
Sapodilla	150
Italian squash	150
Sweetpotato	400
Tomato	150

(2) *Pest specific doses.* Any fruits or vegetables not listed in paragraph (a)(1) of this section that are required by 7 CFR part 318 to be treated or subjected to inspection to control one or more of the plant pests listed in § 305.31(a) may instead be treated with irradiation. Fruits and vegetables treated with irradiation for plant pests listed in § 305.31(a) must be irradiated at the doses listed in § 305.31(a), and the irradiation treatment must be conducted in accordance with the other requirements of § 305.34.

* * * * *

PART 318—HAWAIIAN AND TERRITORIAL QUARANTINE NOTICES

11. The authority citation for part 318 would continue to read as follows:

Authority: 7 U.S.C. 7701–7772; 7 CFR 2.22, 2.80, and 371.3.

§ 318.13 [Amended]

12. In § 318.13, paragraph (c) would be amended by removing the words ''leaves in full force and effect § 318.30 which restricts the movement from Hawaii, Puerto Rico, or the Virgin Islands of the United States into or through any other State or certain Territories or Districts of the United States of all varieties of sweetpotatoes (Ipomoea batatas Poir.). It also''.

13. Section 318.13–1 would be amended as follows:

a. In the definition of *compliance agreement*, by removing the words ''§ 318.13–3(b), § 318.13–4(b), or § 318.13–4f of this subpart'' and adding the words ''§ 318.13(b) or § 318.13–4(b) of this subpart or § 305.34 of this chapter'' in their place.

b. By revising the definition of *inspector* to read as set forth below.

§ 318.13–1 Definitions.

* * * * *

Inspector. Any individual authorized by the Administrator of APHIS or the Commissioner of Customs and Border Protection, Department of Homeland Security, to enforce the regulations in this part.

* * * * *

§ 318.13–2 [Amended]

14. In § 318.13–2, in paragraph (b), the list of articles would be amended by adding, in alphabetical order, a new entry for ''Sweetpotato (Ipomoea batatas Poir.).''

15. Section 318.13–3 would be amended as follows:

a. Paragraph (b)(3) would be revised to read as set forth below.

b. A new paragraph (b)(4) would be added to read as set forth below.

§ 318.13–3 Conditions of movement.

* * * * *

(b) * * *

(3) Untreated fruits and vegetables from Hawaii may be moved interstate for irradiation treatment on the mainland United States if the provisions of § 305.34 are met and if the fruits and vegetables are accompanied by a limited permit issued by an inspector in accordance with § 318.13–4(c). Untreated bananas from Hawaii may be moved interstate for irradiation treatment on the mainland United States if the provisions of § 318.13–4i(b) are met and if the bananas are accompanied by a limited permit issued by an inspector in accordance with § 318.13–4(c). The limited permit will be issued only if the inspector examines the shipment and determines that the shipment has been prepared in compliance with the provisions of this subpart.

(4) Untreated sweetpotatoes from Hawaii may be moved interstate for vapor heat treatment on the mainland United States if the provisions of § 318.13–4e are met and if the sweetpotatoes are accompanied by a limited permit issued by an inspector in accordance with § 318.13–4(c). The limited permit will be issued only if the inspector examines the shipment and determines that the shipment has been prepared in compliance with the provisions of this subpart.

* * * * *

§ 318.13–4b [Amended]

16. In § 318.13–4b, paragraph (b) would be amended as follows:

a. By adding the words ''or vegetables'' after the word ''fruits'' each time it occurs.

b. By removing the words ''fruit flies'' and adding the words ''plant pests'' in their place.

c. By adding the word ''sweetpotatoes,'' after the word ''rambutan,''.

17. A new § 318.13–4d would be added to read as follows:

§ 318.13–4d Vapor heat treatment of sweetpotatoes from Hawaii.

(a) Vapor heat treatment, carried out in accordance with the provisions of this section, is approved as a treatment for sweetpotato from Hawaii.

(b) Sweetpotatoes may be moved interstate from Hawaii in accordance with this section only if the following conditions are met: [2]

[2] Sweetpotatoes may also be moved interstate from Hawaii in accordance with § 305.34 of this chapter or after fumigation with methyl bromide

Continued

(1) The sweetpotatoes must be treated in accordance with the vapor heat treatment schedule specified in § 305.24.

(2) The sweetpotatoes must be sampled, cut, and inspected and found to be free of the ginger weevil (*Elytrotreinus subtruncatus*). Sampling, cutting, and inspection must be performed under conditions that will prevent any pests that may emerge from the sampled sweetpotatoes from infesting any other sweetpotatoes intended for interstate movement in accordance with this section.

(3) The sweetpotatoes must be inspected and found to be free of the gray pineapple mealybug (*Dysmicoccus neobrevipes*) and the Kona coffee-root knot nematode (*Meloidogyne konaensis*).

(4)(i) Sweetpotatoes that are treated in Hawaii must be packaged in the following manner:

(A) The cartons must have no openings that will allow the entry of fruit flies and must be sealed with seals that will visually indicate if the cartons have been opened. They may be constructed of any material that prevents the entry of fruit flies and prevents oviposition by fruit flies into the fruit in the carton.[3]

(B) The pallet-load of cartons must be wrapped before it leaves the treatment facility in one of the following ways:

(*1*) With polyethylene sheet wrap;

(*2*) With net wrapping; or

(*3*) With strapping so that each carton on an outside row of the pallet load is constrained by a metal or plastic strap.

(C) Packaging must be labeled with treatment lot numbers, packing and treatment facility identification and location, and dates of packing and treatment.

(ii) Cartons of untreated sweetpotatoes that are moving to the mainland United States for treatment must be shipped in shipping containers sealed prior to interstate movement with seals that will visually indicate if the shipping containers have been opened.

(5)(i) *Certification on basis of treatment.* A certificate shall be issued by an inspector for the movement of sweetpotatoes from Hawaii that have been treated and handled in Hawaii in accordance with this section. To be certified for interstate movement under this section, sweetpotato from Hawaii must be sampled, cut, and inspected by an inspector and found by an inspector to be free of the ginger weevil (*Elytrotreinus subtruncatus*) and inspected and found by an inspector to be free of the gray pineapple mealybug (*Dysmicoccus neobrevipes*), and the Kona coffee-root knot nematode (*Meloidogyne konaensis*) before undergoing vapor heat treatment in Hawaii.

(ii) *Limited permit.* A limited permit shall be issued by an inspector for the interstate movement of untreated sweetpotato from Hawaii for treatment on the mainland United States in accordance with this section. To be eligible for a limited permit under this section, untreated sweetpotato from Hawaii must be sampled, cut, and inspected in Hawaii by an inspector and found by an inspector to be free of the ginger weevil (*Elytrotreinus subtruncatus*) and inspected and found by an inspector to be free of the gray pineapple mealybug (*Dysmicoccus neobrevipes*), and the Kona coffee-root knot nematode (*Meloidogyne konaensis*).

18. Section 318.13–4f would be revised to read as set forth below.

§ 318.13–4f Irradiation treatment of certain fruits and vegetables from Hawaii.

Irradiation, carried out in accordance with the provisions in § 305.34 of this chapter, is approved as a treatment for the following fruits and vegetables: Abiu, atemoya, bell pepper, carambola, eggplant, litchi, longan, mango, papaya, pineapple (other than smooth Cayenne), rambutan, sapodilla, Italian squash, sweetpotato, and tomato. Any other fruits or vegetables that are required by this subpart to be treated or subjected to inspection to control one or more of the plant pests listed in § 305.31(a) of this chapter may instead be treated with irradiation. Fruits and vegetables treated with irradiation for plant pests listed in § 305.31(a) must be irradiated at the doses listed in § 305.31(a), and the irradiation treatment must be conducted in accordance with the other requirements of § 305.34.

(Approved by the Office of Management and Budget under control number 0579–0198)

19. Section 318.13–4i would be amended as follows:

a. By revising the section heading to read as set forth below.

b. By redesignating paragraphs (a), (b), (c), and (d) as paragraphs (a)(1), (a)(2), (a)(3), and (a)(4), respectively, and by designating the introductory text of the section as paragraph (a), introductory text.

c. By adding a new paragraph (b) to read as set forth below.

§ 318.13–4i Conditions governing the movement of bananas from Hawaii.

* * * * *

(b) Bananas of any cultivar or ripeness may also be moved interstate from Hawaii in accordance with the following conditions:

(1) The bananas are irradiated at the minimum dose listed in § 305.31(a) of this part and in accordance with the other requirements in § 305.34 of this part for the Mediterranean fruit fly (*Ceratitis capitata*), the melon fruit fly (*Bactrocera curcurbitae*), the Oriental fruit fly (*Bactrocera dorsalis*), and the green scale (*Coccus viridis*) and are inspected in Hawaii and found to be free of the banana moth (*Opogona sacchari* (Bojen)) by an inspector before or after undergoing irradiation treatment; or

(2) The bananas are irradiated at the minimum dose listed in § 305.31(a) of this part and in accordance with the other requirements in § 305.34 of this part for the Mediterranean fruit fly (*Ceratitis capitata*), the melon fruit fly (*Bactrocera curcurbitae*), and the Oriental fruit fly (*Bactrocera dorsalis*) and are inspected in Hawaii and found to be free of the green scale (*Coccus viridis*) and the banana moth (*Opogona sacchari* (Bojen)) before or after undergoing irradiation treatment.

(3)(i) A certificate shall be issued by an inspector for the movement of bananas from Hawaii that have been treated and inspected in Hawaii in accordance with this paragraph § 318.13–4i(b). To be certified for interstate movement under this paragraph, bananas from Hawaii must be treated, inspected, and, if necessary, culled in accordance with the requirements of this paragraph prior to interstate movement from Hawaii.

(ii) A limited permit shall be issued by an inspector for the interstate movement of untreated bananas from Hawaii for treatment on the mainland United States in accordance with this section. To be eligible for a limited permit under this paragraph § 318.13–4i(b), bananas from Hawaii must be inspected in accordance with the requirements of this paragraph prior to interstate movement from Hawaii.

Subpart—Sweetpotatoes [Removed]

20. Subpart—Sweetpotatoes, consisting of §§ 318.30 and 318.30a, would be removed.

§ 318.58 [Amended]

21. In § 318.58, paragraph (d) would be amended by removing the words

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according to treatment schedule T–101–b–3–1, as provided for in § 305.6(a) of this chapter.

[3] If there is a question as to the adequacy of a carton, send a request for approval of the carton, together with a sample carton, to the Animal and Plant Health Inspection Service, Plant Protection and Quarantine, Center for Plant Health Inspection and Technology, 1017 Main Campus Drive, suite 2500, Raleigh, NC 27606.

''leaves in full force and effect § 318.30 which restricts the movement from Hawaii, Puerto Rico, or the Virgin Islands of the United States into or through any other State or certain Territories or Districts of the United States of all varieties of sweetpotatoes (Ipomoea batatas Poir.). It also''.

22. In § 318.58–1, the definition of *inspector* would be revised to read as set forth below.

§ 318.58–1 Definitions.

* * * * *

Inspector. Any individual authorized by the Administrator of APHIS or the Commissioner of Customs and Border Protection, Department of Homeland Security, to enforce the regulations in this part.

* * * * *

§ 318.58–2 [Amended]

23. In § 318.58–2, in paragraph (b)(2), the list of articles would be amended by adding, in alphabetical order, a new entry for ''Sweetpotato (Ipomoea batatas Poir.).''

24. A new section § 318.58–4b would be added to read as set forth below.

§ 318.58–4b Irradiation treatment of fruits and vegetables from Puerto Rico and the U.S. Virgin Islands.

Any fruits or vegetables from Puerto Rico or the U.S. Virgin Islands that are required by this subpart to be treated or subjected to inspection to control one or more of the plant pests listed in § 305.31(a) of this chapter may instead be treated with irradiation. Fruits and vegetables treated with irradiation for plant pests listed in § 305.31(a) must be irradiated at the doses listed in § 305.31(a), and the irradiation treatment must be conducted in accordance with the other requirements of § 305.34.

25. A new section § 318.58–4c would be added to read as follows.

§ 318.58–4c Movement of sweetpotatoes from Puerto Rico to certain ports.

Sweetpotatoes from Puerto Rico may be moved interstate to Atlantic Coast ports north of and including Baltimore, MD, if the following conditions are met:

(a) The sweetpotatoes must be certified by an inspector of the Commonwealth of Puerto Rico as having been grown under the following conditions:

(1) Fields in which the sweetpotatoes have been grown must have been given a preplanting treatment with an approved soil insecticide.

(2) Before planting in such treated fields, the sweetpotoato draws and vine cuttings must have been dipped in an approved insecticidal solution.

(3) During the growing season an approved insecticide must have been applied to the vines at prescribed intervals.

(b) An inspector of the Commonwealth of Puerto Rico must certify that the sweetpotatoes have been washed.

(c) The sweetpotatoes must be graded by inspectors of the Commonwealth of Puerto Rico in accordance with Puerto Rican standards which do not provide a tolerance for insect infestation or evidence of insect injury and found by such inspectors to comply with such standards prior to movement from Puerto Rico.

(d) The sweetpotatoes must be inspected by an inspector and found to be free of the sweetpotato scarabee (*Euscepes postfasciatus* Fairm.).

PART 319—FOREIGN QUARANTINE NOTICES

26. The authority citation for part 319 would continue to read as follows:

Authority: 7 U.S.C. 450 and 7701–7772; 21 U.S.C. 136 and 136a; 7 CFR 2.22, 2.80, and 371.3.

§ 319.56–2 [Amended]

27. In § 319.56–2, paragraph (k) would be amended by removing the words ''11 species of fruit flies and one species of seed weevil'' and adding the words ''plant pests'' in their place.

§ 319.56–2x [Amended]

28. In § 319.56–2x, the introductory text in paragraph (a) would be amended by removing the words ''mango seed weevil *Sternochetus mangiferae* (Fabricus) or for one or more of the following 11 species of fruit flies: *Anastrepha fraterculus, Anastrepha ludens, Anastrepha obliqua, Anastrepha serpentina, Anastrepha suspensa, Bactrocera cucurbitae, Bactrocera dorsalis, Bactrocera tryoni, Bactrocera jarvisi, Bactrocera latifrons,* and *Ceratitis capitata*'' and adding the words ''plant pests listed in § 305.31(a)'' in their place.

Done in Washington, DC, this 3rd day of June 2005.

Elizabeth E. Gaston,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 05–11460 Filed 6–9–05; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Parts 260 and 284

[Docket No. RM05–12–000]

Modification of Natural Gas Reporting Regulations

May 27, 2005.

AGENCY: Federal Energy Regulatory Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Federal Energy Regulatory Commission (Commission) is proposing to amend its regulations to standardize the filing format for reporting natural gas service interruptions and emergency natural gas sale, transportation and exchange. The Commission is also proposing to modernize the filing method, develop a tracking method for filings, and develop an electronic notification system to notify appropriate Commission staff when the information is filed with the Commission. In addition, the Commission seeks comment on affording Critical Energy Infrastructure Information (CEII) protection where applicable. These modifications are the result of a review conducted by the Commission's Information Assessment Team (FIAT) of the Commission's current information collections by evaluating their original purposes and current uses, and to propose ways to reduce the reporting burden on industry through the elimination, reduction, streamlining or reformatting of current collections. The modification of the regulations to modernize the filing method and standardize the filing format should streamline the process and reduce the burden of filing information under FERC–576 ''Report of Natural Gas Service Interruptions'' and FERC–588 ''Emergency Natural Gas Sale, Transportation and Exchange Transactions.'' In addition, the Commission proposes to provide CEII protection for the information contained on both information collection requirements and seeks comment on this proposal. The Commission believes these modifications will not in any way prejudice the rights of any participant in those proceedings or anyone interested in the Commission's natural gas program.

DATES: Comments are due July 25, 2005.

ADDRESSES: Comments may be filed electronically via the eFiling link on the Commission's Web site at *http://www.ferc.gov.* Commenters unable to

file comments electronically must send an original and 14 copies of their comments to: The Federal Energy Regulatory Commission, Office of the Secretary, 888 First Street, NE., Washington, DC 20426. Refer to the Comment Procedures section of the preamble for additional information on how to file comments.

FOR FURTHER INFORMATION CONTACT:

Michael Miller (Technical Information), Office of Executive Director, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, (202) 502–8415.

Michael McGehee (Technical Information), Office of Energy Projects, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, (202) 502–8962.

Jacqueline Holmes (Legal Information), Office of the General Counsel, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, (202) 502–8198.

SUPPLEMENTARY INFORMATION:

Introduction

The Federal Energy Regulatory Commission (Commission) has reviewed its natural gas regulations in order to determine whether they contain any outdated requirements or impose any unnecessary burdens on persons subject to the Commission's jurisdiction. This review was conducted by the FERC Information Assessment Team (FIAT) that was tasked by the Chairman to assess the Commission's information needs. Goal 2 of the tasks identified by the team to meet this mission included identifying all of the Commission's current information collections, through forms and filing requirements (electric, hydropower, natural gas, oil and general), and evaluate their original purposes and current uses, and propose ways to reduce the reporting burden on industry through elimination, reduction, streamlining or reformatting of current collections. The modification of the regulations proposed in this rule will modernize the filing method and standardize the filing format to ensure greater filing efficiency for the information filed under FERC–576 ''Report of Natural Gas Service Interruptions'' and FERC–588 ''Emergency Natural Gas Sale, Transportation and Exchange Transactions.'' In addition, because information filed under both information collections reference the location of energy facilities, the Commission is proposing to limit access to this information under its Critical Energy Infrastructure Information (CEII) procedures. The Commission believes that these modifications would not in any way prejudice the rights of any participant in those proceedings or anyone interested in the Commission's natural gas program.

Background

1. Under the Natural Gas Act (NGA) (Public Law 75–688) [1] a natural gas company must obtain the Commission's authorization to engage in the transportation or exchange of natural gas in interstate commerce. The Commission oversees the continuity of service in the transportation of natural gas in interstate commerce. Under section 7(d) of the NGA,[2] the Commission may issue a temporary certificate in cases of emergency to ensure maintenance of adequate service or to serve particular customers without notice or hearing. Section 10(a) of the NGA [3] requires natural gas pipeline companies to file reports with the Commission as prescribed by rules or regulations or by order as appropriate, to assist the Commission in performing its regulatory duties. The provisions of section 16 of the NGA [4] authorize the Commission to prescribe forms, statements, declarations and reports, including the information they are to contain and the time frames for filing the information.

2. The information filed under FERC–576 ''Report of Natural Gas Service Interruptions'' notifies the Commission in a timely manner of any interruption to service or possible hazard to public health or safety. The Commission, in response to timely notification of a serious interruption, may contact other pipelines to determine available supply, and if necessary, authorize transportation or construction of facilities to alleviate the problem. The information collected identifies serious interruptions of service to any wholesale customer involving facilities operated under the Commission's certificate authorization. The information collected may include: (1) The date of service interruption; (2) the date of reporting of the interruption to the Commission; (3) location of the interruption; (4) brief description of the facility involved and the cause of the interruption; (5) customer(s) affected; (6) duration of the interruption, and (7) volumes of natural gas interrupted.

3. FERC–588 ''Emergency Natural Gas Sale, Transportation and Exchange Transactions'' is also authorized by the provisions of the NGA. However, section 7(c)(1)(B) of the NGA exempts from certificate requirements ''temporary acts or operations for which the issuance of a certificate will not be required in the public interest.'' [5] The Natural Gas Policy Act (NGPA) (Public Law 95–621) [6] also provides for the reporting of non-certificated interstate transactions involving intrastate pipelines and local distribution companies.

4. An emergency is defined as any situation in which an actual or expected shortage of gas supply or capacity would require an interstate pipeline company, intrastate pipeline company, local distribution company or Hinshaw pipeline to curtail deliveries of gas or provide less than the projected level of service to any customer. These situations include a sudden, unanticipated loss of natural gas supply or capacity, sudden, anticipated loss of natural gas supply or capacity, or any situation in which the participant, in good faith, determines that immediate action is required for the protection of life or health or the maintenance of physical property. Respondents are to file a report within forty-eight hours after the commencement of the transportation, sale or exchange of deliveries of natural gas commence, a request to extend the sixty-day term of the emergency transportation, if needed, and a termination report.

Discussion

5. In this Notice of Proposed Rulemaking (NOPR) the Commission is proposing to amend parts 260 and 284 of its regulations governing interruptions of natural gas service to wholesale customers involving certificated facilities (18 CFR 260.9) and the emergency reconstruction of certificated facilities (18 CFR 284.270).

6. The Commission intends to modernize the filing method and to assist jurisdictional entities when filing information in response to the requirements of 18 CFR 260.9 ''Report by natural gas pipeline companies on service interruptions occurring on the pipeline system'' and 18 CFR subpart I ''Emergency natural gas sale, transportation, and exchange transactions.'' The Commission will provide for the electronic submission of data, and will standardize the filing format. In addition, the Commission proposes to develop an internal tracking mechanism to provide staff with timely information on the submission of

[1] 15 U.S.C. 717–717w. (2000).

[2] 15 U.S.C. 717f. (2000).

[3] 15 U.S.C. 717i. (2000).

[4] 15 U.S.C. 717o. (2000).

[5] 15 U.S.C. 717f. (2000).

[6] 15 U.S.C. 3301–3432. (2000).

reports for service interruptions and emergency natural gas transaction reports. The latter, as required by 18 CFR 284.270, calls for the submission of forty-eight hour reports for sales transactions, transportation, exchanges and the termination reports.

7. The current requirements of 18 CFR 260.9 direct that natural gas pipeline companies must report to the Commission serious service interruptions to communities, major Government installations and large industrial plants outside of communities, or interruptions that the pipeline considers to be significant. The pipeline must notify the Commission of the interruption with the following information: (1) The location of the interruption; (2) the time of the interruption; (3) the customers affected by the interruption and (4) the emergency actions taken to maintain the service. The pipeline must also provide the Commission with a copy of the failure report filed with the Department of Transportation, and the pipeline must file the interruption report with the state commissions in the affected states. Natural gas pipeline companies currently submit this information in hardcopy as well as any electronic means, including facsimile transmission or telegraph.

8. The information provided for under 18 CFR 284.270 of the Commission's regulations permits the Commission to determine whether an emergency gas sale, transportation or exchange qualifies for an exemption under section 7(c) of the NGA. The information must be filed within 48 hours after an emergency transaction begins, and within 30 days after termination of the transaction. The filer must also submit a report with the U.S. Department of Transportation and may use the telegraph as a medium for transmitting this information.

9. Because the telegraph is an outdated method for submitting this information, the Commission proposes to require instead the electronic submission of the information required in both 18 CFR 260.9 and 18 CFR 284.270. For Internet filing provisions, see 18 CFR 385.2003 (c). The benefits of having this information filed electronically include efficient delivery of the information, immediate confirmation to the filer of the Commission's receipt of the information, and almost immediate access by Commission staff. The electronic submission of information will reduce the number of data entry errors, permit Commission staff to conduct analysis in a timely manner, and provide for the storage of information on optical storage media, thus saving valuable storage. Electronic reporting will also provide time and resource savings for all parties by reducing the number of personnel needed to submit paper filings, particularly since it will eliminate paper processing and mailing. All parties, including the Commission, will benefit by having current data and the integrity of the data will increase because jurisdictional entities and the Commission will be able to correct the errors more promptly.

10. In Order No. 630 [7], the Commission issued procedures for gaining access to CEII, which would not otherwise be made available under the Freedom of Information Act.[8] These procedures made in the aftermath of the September 11, 2001 terrorist attacks, and instituted to restrict unrestrained access to certain types of information because of the threat of terrorism, keep sensitive infrastructure information out of the public domain. By placing restrictions on the use of this information, the Commission will decrease the likelihood terrorists could use such information to plan or execute terrorist attacks. The Commission defines CEII as information about ''existing or proposed critical infrastructure that: (i) Relates to the production, generation, transportation, transmission, or distribution of energy; (ii) could be useful to a person planning an attack on critical infrastructure; (iii) is exempt from mandatory disclosure under the Freedom of Information Act; and, (iv) does not simply give the location of critical infrastructure.'' (18 CFR 388.113 (c)(1)) Critical infrastructure means ''existing or proposed systems and assets, whether physical or virtual, the incapacity or destruction of which would negatively affect security, economic security, public health or safety, or any combination of these matters.'' (18 CFR 388.113(c)(2)) In submitting information under both 18 CFR 260.9 and 284.270, pipelines must provide descriptions of the facilities and their location in order to describe why there is an interruption of service or the measures that they are taking to reconstruct the pipeline. If this information remained publicly available, it could provide those planning or executing terrorist attacks with an opportunity to take advantage of vulnerabilities in the energy infrastructure. It is for this reason the Commission seeks comment on placing the information filed in response to 18 CFR 260.9 and 18 CFR 284.270 under CEII protection. CEII may be released to a requester with a legitimate need for the information who is willing to abide by an appropriate non-disclosure agreement. See 18 CFR 3881.113.

Information Collection Statement

11. The Office of Management and Budget (OMB) regulations require OMB to approve certain information collection requirements imposed by agency rule.[9] Comments are solicited on the Commission's need for this information, whether the information will have practical utility, the accuracy of the provided burden estimates, ways to enhance the quality, utility and clarity of the information to be collected, and any suggested methods for minimizing respondents' burden, including the use of automated information techniques.

12. Estimated Annual Burden

Data collection	Number of respondents	Number of responses	Number of hours per response	Total annual hours
FERC–576	22	1	1	22
FERC–588	8	1	10	80
Totals				102

[7] *Critical Energy Infrastructure Information,* 68 FR 9857 (March 3, 2003), FERC Stats. & Regs. ¶31,140 (2003).

[8] 5 U.S.C. 552. (2000).

[9] 5 CFR 1320.11.

Title: Report of Service Interruptions (FERC–576). Emergency Natural Gas Sale, Transportation & Exchange (FERC–588).

Action: Proposed Collections.

OMB Control Nos. 1902–0004 & 1902–0144.

Respondents: Businesses or other for profit.

Frequency of Responses: On occasion.

Necessity of the Information: The proposed regulations will revise the reporting requirements for service interruptions and emergency transactions to streamline the requirements and reduce the burden for the respondents. The information filed with the Commission informs it of serious natural gas pipeline service interruptions and also of the need for emergency reconstruction of natural gas pipelines or the need to sell, transport or make exchanges due to actual or expected shortages of gas supply.

Internal Review: The Commission has reviewed the proposed amendments to its regulations to modify the filing method, standardize the format and create an internal tracking mechanism for Commission staff. The revisions to the regulations will provide more effective and efficient information by providing current data by electronic submission. This method of filing will reduce data errors and thus preserve the integrity of the data. The Commission will be able to conduct further analysis of filed reports in a more timely fashion and expedite dissemination to Commission staff to ensure a timely response. The Commission also proposes to change the availability of the information to the public by classifying it as subject to CEII protection and seeks comment on this proposal. By invoking this protection, the Commission seeks to minimize the available information on vulnerabilities in the energy infrastructure to those persons who either plan or will execute a terrorist attack. The Commission has assured itself, by means of internal review, that there is specific, objective support for the burden estimates associated with the information collection requirements.

Interested persons may obtain information on the information requirements by contacting the following: The Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426 (Attention: Michael Miller, Office of the Executive Director, phone (202) 502–8415, fax: (202) 273–0873, e-mail: *michael.miller@ferc.gov*).

For submitting comments concerning the collection of information(s) and the associated burden estimate(s), please send your comments to the contact listed above and to the Office of Management and Budget, Office of Information and Regulatory Affairs, Washington, DC 20503, (Attention: Desk Officer for the Federal Energy Regulatory Commission, phone: (202) 395–4650, fax: (202) 395–7285).

Environmental Analysis

13. The Commission is required to prepare an Environmental Assessment or an Environmental Impact Statement for any action that may have a significant adverse effect on the human environment.[10] The Commission has categorically excluded certain actions from this requirement as not having a significant effect on the human environment. Included in the exclusion are rules that are clarifying, corrective, or procedural or that do not substantially change the effect of the regulations being amended.[11] This proposed rule, if finalized, is procedural in nature and therefore falls under this exception. Therefore, no environmental consideration would be necessary.

Regulatory Flexibility Act Certification

14. The Regulatory Flexibility Act of 1980 (RFA)[12] generally requires a description and analysis of final rules that will have significant economic impact on a substantial number of small entities.[13] The Commission is not required to make such an analysis if a rule would not have such an effect.

15. The Commission does not think that the proposed amendments to its regulations would have such an impact on small entities. Based on past experience, most of the pipelines filing either an interruption service report or an emergency transaction report under the proposed regulations would be entities that do not meet the RFA's definition of a small entity. Further, if the proposed regulations are adopted, all pipelines, including small entities, should benefit through reduced staffing and processing costs by being able to submit this information electronically. Therefore, the Commission certifies that this rule will not have a significant impact on a substantial number of small entities.

Comment Procedures

16. The Commission invites interested persons to submit comments on the matters and issues that it proposes to adopt, including any related matters or alternative proposals that commenters may wish to discuss. Comments are due July 25, 2005. Comments must refer to Docket No. RM05–12–000, and must include the commenter's name, the organization they represent, if applicable, and their address in their comments.

17. Comments may be filed electronically via the eFiling link on the Commission's Web site at *http://www.ferc.gov.* The Commission accepts most standard word processing formats and commentors may attach additional files with supporting information in certain other file formats. Commenters filing electronically do not need to make a paper filing. Commenters that are not able to file comments electronically must send an original and 14 copies of their comments to: The Federal Energy Regulatory Commission, Office of the Secretary, 888 First Street NE., Washington, DC, 20426.

18. All comments will be placed in the Commission's public files and may be viewed, printed, or downloaded remotely as described in the Document Availability section below. Commentors commenting on this proposal are not required to serve copies of their comments on other commenters.

Document Availability

19. In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the Internet through FERC's Home Page (*http://www.ferc.gov*) and in FERC's Public Reference Room during normal business hours (8:30 a.m. to 5 p.m. Eastern time) at 888 First Street, NE., Room 2A, Washington, DC 20426.

20. From FERC's Home Page on the Internet, this information is available in the eLibrary. The full text of this document is available in the eLibrary both in PDF and Microsoft Word format for viewing, printing, and/or downloading. To access this document in eLibrary, type the docket number, excluding the last three digits of this document, in the docket number field.

[10] Order No. 486, *Regulations Implementing the National Environmental Policy Act,* 52 FR 47897 (Dec. 17, 1987), FERC Stats. & Regs. Preambles 1986–1990 ¶ 30,783 (1987).

[11] 18 CFR 380.4(a)(2)(ii).

[12] 5 U.S.C. 601–612 (2000).

[13] The RFA definition of ''small entity'' refers to the definition provided in the Small Business Act, which defines a ''small business concern'' as a business which is independently owned and operated and which is not dominant in its field of operation. 15 U.S.C. 632 (2000). The Small Business Size Standards component of the North American Industry Classification System defines a small pipeline for transportation of natural gas as one that, including its affiliates, did not have total annual revenues for the preceding fiscal years exceeding $6.0 million. 13 CFR 121.201 (Sectors 48–49, Sub sector 486, Pipeline Transportation, North American Industry Classification System, NAICS) (2004).

21. User assistance is available for eLibrary and the FERC's Web site during normal business hours. For assistance contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll-free at (866) 208–3676, or for TTY, contact (202) 502–8659. E-Mail the Public Reference Room at *public.referenceroom@ferc.gov* or 202–502–8371.

List of Subjects

18 CFR Part 260

Statements, Reporting and recordkeeping requirements.

18 CFR Part 284

Natural gas, Reporting and recordkeeping requirements.

By direction of the Commission.

Linda Mitry,

Deputy Secretary.

In consideration of the foregoing, the Commission proposes to amend parts 260 and 284, title 18 of the *Code of Federal Regulations*, as set forth below:

PART 260—STATEMENTS AND REPORT (SCHEDULES)

1. The authority citation for part 260 continues to read as follows:

Authority: 15 U.S.C. 717–717w, 3301–3432; 42 U.S.C. 7101–7352.

2. Amend §260.9 by revising paragraphs (b) introductory text and (e), and by adding a note following paragraph (b)(4) to read as follows:

§ 260.9 Report by natural gas pipeline companies on service interruptions occurring on the pipeline system.

* * * * *

(b) *Reporting requirement.* Natural gas pipeline companies must report such interruptions to service by electronic submission, to the Commission and the Director, Division of Pipeline Certificates, Office of Energy Projects, Federal Energy Regulatory Commission, Washington, DC 20426 (Fax: (202) 502–8625) at the earliest feasible time following such interruption to service, and must state briefly:

* * * * *

Note to paragraph (b): Submit in electronic format in accordance with § 385.2003 of this chapter. This report is an electronic file that is classified as a ''qualified document.'' As a qualified document, no paper copy version of the filing is required unless there is a request for privileged and protected treatment or the document is combined with another document as provided in § 385.2003(c)(3) or (4).

* * * * *

(e) Copies of the report on interruption of service must be sent electronically to the State commission in those States where service has been or might be affected.

PART 284—CERTAIN SALES AND TRANSPORTATION OF NATURAL GAS UNDER THE NATURAL GAS POLICY ACT OF 1978 AND RELATED AUTHORITIES

1. The authority citation for part 284 continues to read as follows:

Authority: 15 U.S.C. 717–717w, 3301–3432; 42 U.S.C. 7101–7352; 43 U.S.C. 1331–1356.

2. Amend §284.270 by adding introductory text and by revising paragraphs (a) introductory text, (b) introductory text, and (c) introductory text to read as follows:

§ 284.270 Reporting requirements.

Each report shall be submitted in electronic format in accordance with § 385.2003 of this chapter. All reports are electronic files classified as ''qualified documents.'' As qualified documents, no paper copy version of the filing is required unless there is a request for privileged and protected treatment or the document is combined with another document as provided in § 385.2003(c)(3) or (4).

(a) *Forty-eight hour report for sales transactions.* Within 48 hours after deliveries of emergency natural gas commence, the purchasing participant must notify the Commission electronically of the sale, stating, in the following sequences:

* * * * *

(b) *Forty-eight hour report for transportation (excluding exchanges).* Within 48 hours after deliveries commence in an emergency natural gas transaction which does not involve the sale of emergency natural gas, the recipient of the emergency natural gas shall notify the Commission electronically of the transportation, stating in the following sequence:

* * * * *

(c) *Forty-eight hour report for exchanges.* Within 48 hours after an exchange transaction for emergency natural gas commences, the initial recipient of the exchange volumes shall notify the Commission electronically of the exchange, stating in the following sequence:

* * * * *

[FR Doc. 05–11543 Filed 6–9–05; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[R05–OAR–2004–OH–0004; FRL–7923–5]

Approval and Promulgation of Implementation Plans; Ohio New Source Review Rules

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule; extension of public comment period.

SUMMARY: EPA is extending the comment period for a proposed rule published May 11, 2005 (70 FR 24734). On May 11, 2005, EPA proposed to conditionally approve revisions to the prevention of significant deterioration (PSD) and nonattainment new source review (NSR) construction permit programs submitted by the Ohio Environmental Protection Agency (OEPA) on September 14, 2004. On December 31, 2002, EPA published revisions to the Federal PSD and NSR regulations in 40 CFR parts 51 and 52 (67 FR 80186). These ''NSR Reform'' regulatory revisions became effective on March 3, 2003, and include provisions for baseline emissions determinations, actual-to-future actual methodology, plantwide applicability limits (PALs), clean units, and pollution control projects (PCPs). EPA proposed to conditionally approve OEPA's revised rules to implement these NSR Reform provisions. In response to a May 19, 2005, request from the Natural Resources Defense Council, EPA is extending the comment period for 60 days.

DATES: The comment period is extended to August 9, 2005.

ADDRESSES: Submit comments, identified by Regional Material in EDocket (RME) ID No. R05–OAR–2004–OH–0004, to: Pamela Blakley, Chief, Air Permits Section, (AR–18J), U.S. Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604. Phone: (312) 886–4447. E-mail: *blakley.pamela@epa.gov*. Additional instructions to comment can be found in the notice of proposed rulemaking published May 11, 2005 (70 FR 24734).

FOR FURTHER INFORMATION CONTACT: Genevieve Damico, Air Permits Section (AR–18J), U.S. Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois, 60604, Telephone Number: (312) 353–4761, e-mail address: *damico.genevieve@epa.gov.*

Dated: June 1, 2005.

Norman Niedergang,

Acting Regional Administrator, Region 5.

[FR Doc. 05–11539 Filed 6–9–05; 8:45 am]

BILLING CODE 6560–50–M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 271

[FRL–7922–7]

Louisiana: Final Authorization of State Hazardous Waste Management Program Revisions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The of State Louisiana has applied to EPA for Final authorization of the changes to its hazardous waste program under the Resource Conservation and Recovery Act (RCRA). EPA proposes to grant Final authorization to the State of Louisiana. In the ''Rules and Regulations'' section of this **Federal Register**, EPA is authorizing the changes by an immediate final rule. EPA did not make a proposal prior to the immediate final rule because we believe this action is not controversial and do not expect comments that oppose it. We have explained the reasons for this authorization in the preamble to the immediate final rule. Unless we get written comments which oppose this authorization during the comment period, the immediate final rule will become effective on the date it establishes, and we will not take further action on this proposal. If we receive comments that oppose this action, we will withdraw the immediate final rule and it will not take effect. We will then respond to public comments in a later final rule based on this proposal. You may not have another opportunity for comment. If you want to comment on this action, you must do so at this time.

DATES: Send your written comments by July 11, 2005.

ADDRESSES: Send written comments to Alima Patterson, Region 6, Regional Authorization Coordinator, (6PD-O), Multimedia Planning and Permitting Division, at the address shown below. You can examine copies of the materials submitted by the State of Louisiana during normal business hours at the following locations: EPA Region 6, 1445 Ross Avenue, Dallas, Texas 75202–2733, phone number (214) 665–6444 ; or Louisiana Department of Environmental Quality, 602 N. Fifth Street, Baton Rouge, Louisiana 70884–2178, phone number (225) 219–3559. Comments may also be submitted electronically or through hand delivery/courier; please follow the detailed instructions in the **ADDRESSES** section of the immediate final rule which is located in the Rules section of this **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Alima Patterson (214) 665–8533.

SUPPLEMENTARY INFORMATION: For additional information, please see the immediate final rule published in the ''Rules and Regulations'section of this **Federal Register**.

Dated: May 13, 2005.

Lawrence E. Starfield,

Acting Regional Administrator, Region 6.

[FR Doc. 05–11468 Filed 6–9–05; 8:45 am]

BILLING CODE 6560–50–P

Notices

Federal Register
Vol. 70, No. 111
Friday, June 10, 2005

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

Submission for OMB Review; Comment Request

June 6, 2005.

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments regarding (a) whether the 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 agency's estimate of burden including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility and clarity of the information to be collected; (d) ways to minimize 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 should be addressed to: Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), *OIRA_Submission@OMB.EOP.GOV* or fax (202) 395–5806 and to Departmental Clearance Office, USDA, OCIO, Mail Stop 7602, Washington, DC 20250–7602. Comments regarding these information collections are best assured of having their full effect if received within 30 days of this notification. Copies of the submission(s) may be obtained by calling (202) 720–8958.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Animal and Plant Health Inspection Service

Title: NAHMS Equine 2005 Study (Equine 2005).

OMB Control Number: 0579–NEW.

Summary of Collection: Collection and dissemination of animal health and poultry data and information is mandated by 7 U.S.C. 391, the Animal Industry Act of 1884, which established the precursor of the Animal and Plant Health Inspection Service (APHIS), Veterinary Services, the Bureau of Animal Industry. APHIS operates the National Animal Health Monitoring System (NAHMS), which collects, on a national basis, statistically valid and scientifically sound data on the prevalence and economic importance of livestock and poultry disease risk factors. APHIS is collecting information that is not available from any other source on the health of the nation's equine population. NAHMS will initiate a national study titled Equine 2005, consisting of two components (an equine event and an on-farm), to collect information on the U.S. equid population.

Need and Use of the Information: APHIS will collect information using two forms. APHIS will use the date collected to: (1) Predict or detect national and regional trends in disease emergence and movement, (2) address emerging issues, (3) determine the economic consequences of disease, and (4) develop trade strategies and support trade decisions. Without the data, APHIS would be less prepared to handle an outbreak of disease.

Description of Respondents: Individuals or households; Farms; Business or other for-profit.

Number of Respondents: 4,360.

Frequency of Responses: Reporting: On occasion.

Total Burden Hours: 4,180.

Ruth Brown,

Departmental Information Collection Clearance Officer.

[FR Doc. 05–11506 Filed 6–9–05; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

June 6, 2005.

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments regarding (a) whether the 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 agency's estimate of burden including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility and clarity of the information to be collected; (d) ways to minimize 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 should be addressed to: Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), *OIRA_Submission@OMB.EOP.GOV* or fax (202) 395–5806 and to Departmental Clearance Office, USDA, OCIO, Mail Stop 7602, Washington, DC 20250–7602. Comments regarding these information collections are best assured of having their full effect if received within 30 days of this notification. Copies of the submission(s) may be obtained by calling (202) 720–8681.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Rural Utilities Service

Title: Request for Mail List Data, RUS Form 87.

OMB Control Number: 0572–0051.

Summary of Collection: The Rural Utilities Service (RUS) is a credit agency of the U.S. Department of Agriculture.

The agency makes loans (direct and guaranteed) to finance electric and telecommunications facilities in rural areas in accordance with the Rural Electrification Act of 1936, 7 U.S.C. 901 as amended, (ReAct). RUS Electric Program provides support to the vast rural American electric infrastructure. RUS' Telecommunications Program makes loans to furnish and improve telephone services and other telecommunications purposes in rural areas.

Need and Use of the Information: RUS will collect information using RUS Form 87, Request for Mail List Data. The information is used for the RUS Electric and Telephone programs to obtain the name and addresses of the borrowers' officers/board of directors and corporate officials, who are authorized to sign official documents. RUS uses the information to assure that (1) accurate, current, and verifiable information is available; (2) correspondence with borrowers is properly directed; and (3) the appropriate officials have signed the official documents submitted.

Description of Respondents: Not-for-profit institutions; Business or other for-profit.

Number of Respondents: 1,383.

Frequency of Responses: Reporting: On occasion.

Total Burden Hours: 346.

Charlene Parker,

Departmental Information Collection Clearance Officer.

[FR Doc. 05–11507 Filed 6–9–05; 8:45 am]

BILLING CODE 3410–15–P

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

June 7, 2005.

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments regarding (a) whether the 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 agency's estimate of burden including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility and clarity of the information to be collected; (d) ways to minimize 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 should be addressed to: Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), *OIRA_Submission@OMB.EOP.GOV* or fax (202) 395–5806 and to Departmental Clearance Office, USDA, OCIO, Mail Stop 7602, Washington, DC 20250–7602. Comments regarding these information collections are best assured of having their full effect if received within 30 days of this notification. Copies of the submission(s) may be obtained by calling (202) 720–8681.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Rural Business Service

Title: 7 CFR 1951–R, Rural Development Loan Servicing.

OMB Control Number: 0570–0015.

Summary of Collection: The Rural Development (RD) Loan Servicing was legislated in 1985 under Section 1323 of the Food and Security Act of 1985. This action is needed to implement the provision of Section 407 of the health and Human Services Act of 1986, which amended Section 1323 of the Food Security Act of 1985. Subpart R of part 1951 contains regulations for servicing and liquidating existing loans previously approved and administered by the U.S. Department of Health and Human Services under 45 CFR Part 1076 and transferred from HHS to the Department of Agriculture. This subpart contains regulation for servicing and liquidating loans made by RD, successor to the Farmers Home Administration under the Intermediary Relending Program to eligible intermediaries and applies to ultimate recipients and other involved parties.

Need and Use of the Information: RD will collect information from the Intermediary, *i.e.* assets and liabilities, income statement and a summary of the Intermediary's lending and guarantee program. The information is vital to RD for the Agency to make credit and financial analysis decisions based on financial information provided by the Intermediary.

Description of Respondents: Not-for-profit institutions; Business or other for-profit.

Number of Respondents: 420.

Frequency of Responses: Reporting: On occasion; Quarterly; Semi-annually; Annually.

Total Burden Hours: 11,235.

Charlene Parker,

Departmental Information Collection Clearance Officer.

[FR Doc. 05–11508 Filed 6–9–05; 8:45 am]

BILLING CODE 3410–XT–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. 05–036–1]

Notice of Request for Approval of an Information Collection; Cooperative Wildlife Damage Management Programs

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: New information collection; comment request.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Animal and Plant Health Inspection Service's intention to request approval by the Office of Management and Budget of an information collection associated with wildlife damage management programs.

DATES: We will consider all comments that we receive on or before August 9, 2005.

ADDRESSES: You may submit comments by any of the following methods:

EDOCKET: Go to *http://www.epa.gov/feddocket* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Once you have entered EDOCKET, click on the ''View Open APHIS Dockets'' link to locate this document.

Postal Mail/Commercial Delivery: Please send four copies of your comment (an original and three copies) to Docket No. 05–036–1, Regulatory Analysis and Development, PPD, APHIS, Station 3C71, 4700 River Road Unit 118, Riverdale, MD 20737–1238. Please state that your comment refers to Docket No. 05–036–1.

Reading Room: You may read any comments that we receive on this docket in our reading room. The reading room is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue, SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday

through Friday, except holidays. To be sure someone is there to help you, please call (202) 690–2817 before coming.

Other Information: You may view APHIS documents published in the **Federal Register** and related information on the Internet at *http://www.aphis.usda.gov/ppd/rad/webrepor.html.*

FOR FURTHER INFORMATION CONTACT: For information on the information collection associated with wildlife damage management programs, contact Mr. Robert P. Myers, Wildlife Biologist, Wildlife Services, APHIS, 4700 River Road Unit 87, Riverdale, MD 20737; (301) 734–7921. For copies of more detailed information on the information collection, contact Mrs. Celeste Sickles, APHIS' Information Collection Coordinator, at (301) 734–7477.

SUPPLEMENTARY INFORMATION:

Title: Cooperative Wildlife Damage Management Programs.

OMB Number: 0579–XXXX.

Type of Request: Approval of a new information collection.

Abstract: As authorized by the Act of 1931 (7 U.S.C. 426–426c; 46 Stat. 1468) as amended, the Secretary of Agriculture may conduct activities and enter into agreements with States, local jurisdictions, individuals, public and private agencies, organizations, and institutions in the control of nuisance mammals and birds and those mammal and bird species that are reservoirs for zoonotic diseases.

Wildlife Services (WS) of the Animal and Plant Health Inspection Service (APHIS), U.S. Department of Agriculture (USDA), cooperates with Federal agencies, State and local governments, and private individuals to research and implement the best methods of managing conflicts between wildlife and human health and safety, agriculture, property, and natural resources.

As part of the WS program, WS enters into agreements to document the terms and conditions for cooperating with parties outside of APHIS.

In the normal course of business in response to requests for assistance in managing wildlife damage, WS collects information about organizations, industry, Federal and non-Federal entities, and members of the public as part of its program. Program activities usually consist of either cooperative direct control or technical assistance programs. In the former, WS provides goods, services, and expertise to address wildlife damage. Clients must reimburse USDA for expenses and time spent by WS to conduct these kinds of programs. In the latter, WS gives advice in the form of telephone consultations, personal onsite consultations, training sessions, demonstration projects, etc. WS usually provides only technical expertise in these activities, and the client usually conducts whatever activities are likely to manage the wildlife damage occurring. Such activities are usually free to the public.

All persons who receive assistance from WS are referred to as ''cooperators,'' and any information provided by clients to WS is voluntary.

Information is used by the agency to:

Identify cooperators appropriately.

Identify lands on which WS personnel will work.

Differentiate between cooperators (*i.e.*, property owners, land managers, or resource owners) who request assistance to manage damage caused by wildlife.

Identify the land areas on which wildlife damage management activities would be conducted.

Identify the relationship between resources or property and the damage caused by wildlife.

Determine the methods or damage management activities to deal with the damage.

Establish a record that a cooperative agreement has been entered into with a cooperator.

Document that permission has been obtained from landowners to go on the cooperator's property.

Record wildlife damage occurrences on cooperator's property and steps to address them.

Record occurrences which may have affected non-target species or humans during, or related to, WS project actions.

Determine satisfaction with service to help WS evaluate, modify, and improve its programs.

We are asking the Office of Management and Budget (OMB) to approve our use of these information collection activities for 3 years.

The purpose of this notice is to solicit comments from the public (as well as affected agencies) concerning this information collection. These comments will help us:

(1) Evaluate whether 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) Evaluate the accuracy of our estimate of the burden of the information collection, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the information collection on those who are to respond, through use, as appropriate, of automated, electronic, mechanical, and other collection technologies, *e.g.*, permitting electronic submission of responses.

Estimate of burden: The public reporting burden for this collection of information is estimated to average 0.0558761 hours per response.

Respondents: Federal, State, and local agencies and the public who request services from WS or engage in wildlife damage management projects with WS.

Estimated annual number of respondents: 95,000.

Estimated annual number of responses per respondent: 0.996.

Estimated annual number of responses: 94,620.

Estimated total annual burden on respondents: 5,287 hours. (Due to averaging, the total annual burden hours may not equal the product of the annual number of responses multiplied by the reporting burden per response.)

All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

Done in Washington, DC, this 6th day of June 2005.

Elizabeth E. Gaston,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. E5–3011 Filed 6–9–05; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Forest Service

Siskiyou County Resource Advisory Committee

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The Siskiyou County Resource Advisory Committee will meet in Yreka, California, June 20, 2005. The meeting will include routine business, a discussion of larger scale projects, and the recommendation for implementation of submitted project proposals.

DATES: The meeting will be held June 20, 2005, from 4 p.m. until 7 p.m.

ADDRESSES: The meeting will be held at the Yreka High School Library, Preece Way, Yreka, California.

FOR FURTHER INFORMATION CONTACT: Bob Talley, RAC Coordinator, Klamath National Forest, (530) 841–4423 or electronically at *rtalley@fs.fed.us*

SUPPLEMENTARY INFORMATION: The meeting is open to the public. Public

comment opportunity will be provided and individuals will have the opportunity to address the Committee at that time.

Dated: June 3, 2005.

Margaret J. Boland,

Designated Federal Official.

[FR Doc. 05–11518 Filed 6–9–05; 8:45 am]

BILLING CODE 3410–11–M

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Additions and Deletions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Additions to and deletions from Procurement List.

SUMMARY: This action adds to the Procurement List a product and a service to be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities, and deletes from the Procurement List products previously furnished by such agencies.

EFFECTIVE DATE: July 10, 2005.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, Jefferson Plaza 2, Suite 10800, 1421 Jefferson Davis Highway, Arlington, Virginia, 22202–3259.

FOR FURTHER INFORMATION CONTACT: Sheryl D. Kennerly, telephone: (703) 603–7740, Fax: (703) 603–0655, or e-mail *SKennerly@jwod.gov.*

SUPPLEMENTARY INFORMATION:

Additions

On March 11, and April 15, 2005, the Committee for Purchase From People Who Are Blind or Severely Disabled published notice (70 FR 12179, and 19924) of proposed additions to the Procurement List.

After consideration of the material presented to it concerning capability of qualified nonprofit agencies to provide the products and services and impact of the additions on the current or most recent contractors, the Committee has determined that the product and service listed below are suitable for procurement by the Federal Government under 41 U.S.C. 46–48c and 41 CFR 51–2.4.

Regulatory Flexibility Act Certification

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 product and service to the Government.

2. The action will result in authorizing small entities to furnish the product and service to the Government.

3. 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 product and service proposed for addition to the Procurement List.

End of Certification

Accordingly, the following product and service are added to the Procurement List:

Product

Glow Plug

NSN: 2920–01–151–3627—Glow Plug.
NPA: Shares Inc., Shelbyville, Indiana.
Contracting Activity: Defense Supply Center Columbus, Columbus, Ohio.

Service

Service Type/Location: Mailing Services, Government Printing Office—Laurel Warehouse, 8610 & 8660 Cherry Lane, Laurel, Maryland.
NPA: Alliance, Inc., Baltimore, Maryland.
Contracting Activity: Government Printing Office, Washington, DC.

Deletions

On April 15, 2005, the Committee for Purchase From People Who Are Blind or Severely Disabled published notice (70 FR 19924) of proposed deletions to the Procurement List.

After consideration of the relevant matter presented, the Committee has determined that the products 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.

Regulatory Flexibility Act Certification

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 may result in additional reporting, recordkeeping or other compliance requirements for small entities.

2. The action may result in authorizing small entities to furnish the products to the Government.

3. 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 products deleted from the Procurement List.

End of Certification

Accordingly, the following products are deleted from the Procurement List:

Products

Flashlight

NSN: 6230–01–513–3288—Flashlight, Aluminum, 5D, Red.
NSN: 6230–01–513–3287—Flashlight, Aluminum, 5D, Blue.
NSN: 6230–01–513–3291—Flashlight, Aluminum, 4D, Blue.
NSN: 6230–01–513–3273—Flashlight, Aluminum, 3D, Red.
NSN: 6230–01–513–3301—Flashlight, Aluminum, 5D, Silver.
NSN: 6230–01–513–3308—Flashlight, Aluminum, 4D, Silver.
NSN: 6230–01–513–3270—Flashlight, Aluminum, 3D, Silver.
NPA: Central Association for the Blind & Visually Impaired, Utica, New York.
Contracting Activity: Office Supplies & Paper Products Acquisition Center, New York, NY.

Pen, Gel, Executive.

NSN: 7520–00-NIB–1491—Pen, Gel, Executive.
NPA: West Texas Lighthouse for the Blind, San Angelo, Texas.
Contracting Activity: Office Supplies & Paper Products Acquisition Center, New York, NY.

Super Disk LS–120 Imation.

NSN: 7045–01–455–2291—Super Disk LS–120 Imation.
NPA: North Central Sight Services, Inc., Williamsport, Pennsylvania.
Contracting Activity: Defense Supply Center Philadelphia, Philadelphia, Pennsylvania.

Test Kit, Oil Condition.

NSN: 6630–01–096–4792—Test Kit, Oil Condition.
NPA: Susquehanna Association for the Blind and Visually Impaired, Lancaster, Pennsylvania.
Contracting Activity: Defense Supply Center Philadelphia, Philadelphia, Pennsylvania.

Sheryl D. Kennerly,

Director, Information Management.

[FR Doc. E5–3009 Filed 6–9–05; 8:45 am]

BILLING CODE 6353–01–P

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 is proposing to add to the Procurement List services

to be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities.

DATES: Comments must be received on or before: July 10, 2005.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, Jefferson Plaza 2, Suite 10800, 1421 Jefferson Davis Highway, Arlington, Virginia 22202–3259.

FOR FURTHER INFORMATION CONTACT: Sheryl D. Kennerly, telephone: (703) 603–7740, Fax: (703) 603–0655, or e-mail *SKennerly@jwod.gov.*

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 proposed actions.

If the Committee approves the proposed additions, the entities of the Federal Government identified in the notice for each service will be required to procure the services listed below from nonprofit agencies employing persons who are blind or have other severe disabilities.

Regulatory Flexibility Act Certification

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. If approved, 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 services to the Government.

2. If approved, the action will result in authorizing small entities to furnish the services to the Government.

3. 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 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.

End of Certification

The following services are proposed for addition to Procurement List for production by the nonprofit agencies listed:

Services

Service Type/Location: Custodial Services, U.S. Department of Agriculture, 150 Central Sector Bldg C2, Warehouse #3, Carolina, Puerto Rico.
NPA: The Corporate Source, Inc., New York, New York.
Contracting Activity: USDA, Animal & Plant Health Inspection Service, Minneapolis, MN.

Service Type/Location: Custodial & Grounds Maintenance, U.S. Secret Service Command Post, 1 Woodland Drive, Plains, Georgia.
NPA: Middle Flint Behavioral HealthCare—Sumter County MR Center, Americus, Georgia.
Contracting Activity: GSA, Property Management Center (4PMB), Atlanta, Georgia.

Service Type/Location: Custodial Services (at the following U.S. Department of Agriculture locations):
USDA, #257 Aduana Street, Mayaguez, Puerto Rico.
USDA, Aguadila Station/Borinquen, Hangar 35–Pax Terminal, Aguadilla, Puerto Rico.
USDA, Eugenio Maria de Hostos International Airport, Main Terminal Building Mayaguez Airport, Mayaguez, Puerto Rico.
USDA, Mercedita International Airport, Main Terminal Building, Mercedita, Puerto Rico.
NPA: The Corporate Source, Inc., New York, New York.
Contracting Activity: USDA, Animal & Plant Health Inspection Service, Minneapolis, MN.

Service Type/Location: Hospital Housekeeping Services, 36th Medical Group Clinic, Andersen AFB, Guam.
NPA: Able Industries of the Pacific, Tamuning, Guam.
Contracting Activity: 36th U.S. Air Force Contracting Squadron/LGCD, Andersen AFB, Guam.

Sheryl D. Kennerly,
Director, Information Management.

[FR Doc. E5–3010 Filed 6–9–05; 8:45 am]
BILLING CODE 6353–01–P

DEPARTMENT OF COMMERCE

Office of the Secretary

Strengthening America's Communities Advisory Committee

AGENCY: Office of the Secretary, Department of Commerce.

ACTION: Notice of open teleconference meeting.

SUMMARY: The Strengthening America's Communities Advisory Committee (the ''Committee'') will convene an open teleconference meeting on Monday, June 27, 2005 to discuss the status of its report and to address other Committee business (as necessary). Members of the public may listen to the meeting by using the teleconference call-in number and pass code provided below.

DATES: Monday, June 27, 2005, beginning at 2:10 p.m. (EDT).

ADDRESSES: *Telephone:* Beginning at 2 p.m. (EDT) on June 27, 2005, members of the public may call 1–888–677–1801 and dial pass code 6594056 to access the teleconference. Pre-registration is not required in advance of the call.

FOR FURTHER INFORMATION CONTACT: Mr. Robert E. Olson, Designated Federal Officer of the Committee, Economic Development Administration, Department of Commerce, Room 7015, 1401 Constitution Avenue, NW., Washington, DC 20230; telephone (202) 482–4495; facsimile (202) 482–2838; e-mail: *saci@eda.doc.gov.* Please note that any correspondence sent by regular mail may be substantially delayed or suspended in delivery, since all regular mail sent to the Department of Commerce (the ''Department'') is subject to extensive security screening. For information about the Initiative, please visit the Department's Web site at *http://www.commerce.gov/SACI/index.htm.*

SUPPLEMENTARY INFORMATION: The Committee will convene a teleconference meeting on Monday, June 27, 2005 to discuss the status of its report and to address other Committee business that may arise during the course of the meeting. Members of the public may listen to the meeting by using the teleconference call-in number and pass code set forth above (*see* **ADDRESSES**/Telephone section above). The Committee will not be receiving public comment during the meeting; however, the Committee welcomes interested persons to submit written comments to the Committee's Designated Federal Officer listed above at any time before or after the meeting. To facilitate distribution of written statements to Committee members prior to the meeting, the Committee suggests that written statements be submitted to the Designated Federal Officer by facsimile or e-mail no later than June 22, 2005.

The prospective agenda for the Committee meeting is as follows:

June 27, 2005

Call to Order

Opening Remarks

Discussion of Draft Report; and

Review and Discussion of Other Committee Issues (as necessary)

This agenda is subject to change. Any changes to the agenda will be posted on the Department's Web site at *http://www.commerce.gov/SACI/index.htm.*

Dated: June 7, 2005.

David Bearden,

Deputy Assistant Secretary of Commerce for Economic Development.

[FR Doc. 05–11583 Filed 6–9–05; 8:45 am]

BILLING CODE 3510–24–P

CORPORATION FOR NATIONAL AND COMMUNITY SERVICE

Information Collection; Submission for OMB Review, Comment Request

AGENCY: Corporation for National and Community Service.

ACTION: Notice.

SUMMARY: The Corporation for National and Community Service (hereinafter the ''Corporation''), has submitted a public information collection request (ICR) entitled the Financial Status Report (FSR) form to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995, Pub. L. 104–13, (44 U.S.C. Chapter 35). Copies of this ICR, with applicable supporting documentation, may be obtained by calling the Corporation for National and Community Service, Ms. Margaret Rosenberry at (202) 606–5000, ext. 124. Individuals who use a telecommunications device for the deaf (TTY–TDD) may call (202) 565–2799 between 8:30 a.m. and 5 p.m. eastern time, Monday through Friday.

ADDRESSES: Comments may be submitted, identified by the title of the information collection activity, to the Office of Information and Regulatory Affairs, Attn: Ms. Katherine Astrich, OMB Desk Officer for the Corporation for National and Community Service, by any of the following two methods within 30 days from the date of publication in this **Federal Register:**

(1) By fax to: (202) 395–6974, Attention: Ms. Katherine Astrich, OMB Desk Officer for the Corporation for National and Community Service; and

(2) Electronically by e-mail to: *Katherine_T._Astrich@omb.eop.gov.*

SUPPLEMENTARY INFORMATION: The OMB is particularly interested in comments which:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Corporation, including whether the information will have practical utility;
- Evaluate 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;
- Propose ways to enhance the quality, utility, and clarity of the information to be collected; and
- Propose ways to minimize 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.

Comments

A 60-day public comment Notice was published in the **Federal Register** on February 28, 2005. This comment period ended April 28, 2004. No public comments were received from this notice.

Description: The Corporation is seeking approval of the modified Financial Status Report form to review and approve federal and non-federal expenditure of funds by Grants Management Specialists in the Office of Grants Management, in order to determine the grantee is meeting their statutory match requirements.

The Financial Status Report form will be completed electronically in the Corporation's grant system (eGrants) to evaluate their financial performance of federal funds. This modified form is also used exclusively to monitor our grantee's compliance levels required for the AmeriCorps program. The cost share requirements must indicate a minimum of 15% cash for members support expenses and at least 33% of program operating expenses. Financial Status Reports are requested semi-annually. The information collected has proven to be an effective tracking tool to maintain adequate financial management integrity.

Type of Review: Renewal.

Agency: Corporation for National and Community Service.

Title: AmeriCorps Financial Status Report; Standard Form 269A (Modified).

OMB Number: 3045–0103.

Agency Number: SF424–NSSC.

Affected Public: Current and prospective recipients of AmeriCorps program grants.

Total Respondents: 732.

Frequency: Semi-annually, with a few exceptions.

Average Time Per Response: 2 hours.

Estimated Total Burden Hours: 2,928 hours.

Total Burden Cost (capital/startup): None.

Total Burden Cost (operating/maintenance): None.

Dated: June 3, 2005.

Doug Gerry,

Acting Director of Office of Grants Management.

[FR Doc. 05–11485 Filed 6–9–05; 8:45 am]

BILLING CODE 6050–$$–P

DEPARTMENT OF DEFENSE

Department of the Army

Board of Visitors, United States Military Academy (USMA)

AGENCY: Department of the Army, DoD.

ACTION: Notice of open meeting.

SUMMARY: In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), announcement is made of the following committee meeting:

Name of Committee: Board of Visitors, United States Military Academy.

Date: Friday, July 15, 2005.

Place of Meeting: Superintendent's Conference Room, Taylor Hall, Building 600, West Point, NY.

Start Time of Meeting: Approximately 1 p.m.

FOR FURTHER INFORMATION CONTACT: Lieutenant Colonel Shaun T. Wurzbach, United States Military Academy, West Point, NY 10996–5000, (845) 938–4200.

SUPPLEMENTARY INFORMATION: *Proposed Agenda:* Summer Meeting of the Board of Visitors. Review of the Academic, Military and Physical Programs at the USMA. Sub Committee meetings on Academics, Military/Physical and Quality of Life to be held prior to Spring meeting. One closed session pending Secretary of the Army approval.

Brenda S. Bowen,

Army Federal Register Liaison Officer.

[FR Doc. 05–11500 Filed 6–9–05; 8:45 am]

BILLING CODE 3710–08–M

DEPARTMENT OF DEFENSE

Department of the Army; Corps of Engineers

Intent To Prepare a Draft Revised General Reevaluation Report/Second Supplemental Environmental Impact Statement (RGRR/SEIS) for the Modified Water Deliveries to Everglades National Park, Tamiami Trail Feature

AGENCY: Department of the Army, U.S. Army Corps of Engineers, DoD.

ACTION: Notice of intent.

SUMMARY: The Jacksonville District, U.S. Army Corps of Engineers intends to

prepare a Draft Second Supplemental Environmental Impact Statement (DSEIS) for the Tamiami Trail feature of the Modified Water Deliveries to Everglades National Park (MWD) project in Miami-Dade County. The study is a cooperative effort between the U.S. Army Corps of Engineers, Everglades National Park (ENP), the Florida Department of Transportation, and the South Florida Water Management District.

FOR FURTHER INFORMATION CONTACT: Jon Moulding, U.S. Army Corps of Engineers, Planning Division, Environmental Branch, P.O. Box 4970, Jacksonville, FL 32232–0019, by e-mail, *jon.moulding@usace.army.mil*, or by telephone at 904–232–2286.

SUPPLEMENTARY INFORMATION:

a. Authorization: The MWD project in South Florida was authorized by the Everglades National Park Protection and Expansion Act of 1989. Prior to the current study, a Final GRR/SEIS on the project was coordinated with the public in December 2003. The document was withdrawn without a Record of Decision because additional information on costs and benefits required a revision of plan formulation and evaluation.

b. Project Scope: The primary goal of the MWD project is to improve water deliveries to ENP from the Central and Southern Florida project. The Tamiami Trail feature involves means to convey water south under Tamiami Trail, U.S. Highway 41, into Northeast Shark River Slough of ENP. Specific Objectives include passing peak MWD flows under the highway in as natural a way as practicable without adversely affecting the roadbed and public safety.

c. Preliminary Alternatives: The previously examined alternatives will be reevaluated in light of new hydrologic modeling that indicates the need for a higher design water elevation, greater construction costs resulting from increases in market costs of material, concerns for public safety, and the need to raise the profile of any portion of the road that would not be bridged.

d. Issues: The RGRR/SEIS will consider impacts on health and safety, aesthetics and recreation, cultural resources, socio-economic resources, hydrology, water quality, ecosystem habitat, fish and wildlife resources, threatened and endangered species, and construction costs.

e. Scoping: As the nature of the issues have not changed since the previous document was issued, no additional scoping is planned.

f. Public Involvement: Public workshops may be held over the course of the study; the exact location, dates, and times will be announced in public notices and local newspapers. A Public meeting will be held after release of the Draft RGRR/SEIS; the exact location, date, and times will be announced in a public notice and local newspapers.

g. Coordination: The proposed action is in accordance with the Fish and Wildlife Coordination Act (FWCA) of 1958 and the Endangered Species Act (ESA) of 1973. The coordinating agencies include the U.S. Fish and Wildlife Service, Everglades National Park, the Florida Fish and Wildlife Conservation Commission, the Florida Department of Transportation, and the South Florida Water Management District.

h. Other Environmental Review and Consultation: The proposed action would involve evaluation for compliance with guidelines pursuant to Section 404(b) of the Clean Water Act and the National Historic Preservation Act.

i. Agency Role: As cooperating agency, Everglades National Park will provide extensive information and assistance on the resources to be impacted and alternatives.

j. DSEIS Preparation: The integrated draft RGRR, including a DSEIS, is currently estimated for publication in August 2005.

Dated: June 3, 2005.

Stuart J. Appelbaum,

Chief, Planning Division.

[FR Doc. 05–11498 Filed 6–9–05; 8:45 am]

BILLING CODE 3710–AJ–M

DEPARTMENT OF DEFENSE

Department of the Army; Corps of Engineers

Intent To Prepare a Draft Environmental Impact Statement for the Proposed River Islands Project, in San Joaquin County, CA

AGENCY: Department of the Army, U.S. Army Corps of Engineers, DoD.

ACTION: Notice of intent.

SUMMARY: The U.S. Army Corps of Engineers, Sacramento District (Corps), will prepare a Draft Environmental Impact Statement (DEIS) for Corps authorization actions for the proposed River Islands project. The overall project purpose is to construct a large-scale, mixed-use project consisting of residential development, a commercial complex, and which may include open space and recreational amenities, located in San Joaquin County or the south delta area. The DEIS will address impacts such as major changes in the operation and maintenance of a Federal flood control project, navigation, hydrology, water quality, wetlands, endangered species, agricultural resources, transportation, cultural resources, and air quality.

DATES: The projected date for public release of the DEIS is November, 2006. Two public scoping meetings will be held on June 29, 2005, to receive comments on the proposed contents of the DEIS. One meeting will be held during business hours at 1:30 p.m. and the second will be held in the evening at 7 p.m. to accommodate the schedules of participants.

ADDRESSES: The scoping meetings will be held at the Lathrop Community Room, 15453 7th Street, Lathrop, CA 95330. Written comments may be mailed to Ms. Patti Johnson at, 1325 J Street, Room 1480, Sacramento, CA 95814–2922. All comments must be received on or before July 29, 2005.

FOR FURTHER INFORMATION CONTACT: Questions about the proposed action and the DEIS can be answered by Ms. Patti Johnson, telephone (916) 557–6611, or e-mail at *patti.P.Johnson@usace.army.mil.* Please refer to Identification Number 199500412.

SUPPLEMENTARY INFORMATION: River Islands, LLC, (applicant) has applied for Corps authorization under section 404 of the Clean Water Act. The applicant is also requesting the State of California Reclamation Board to seek permission from the Corps Chief of Engineers under 33 U.S.C. 408 to permanently alter federal flood control project levees. The project as proposed would also require Corps authorization under Section 10 of the Rivers and Harbors Act. The project may also require other Federal, State or local authorizations, including bridge permit(s) from the U.S. Coast Guard under Section 9 of the Rivers and Harbors Act.

The proposed project site currently includes agricultural land, forested riparian habitat, and rip-rapped flood control levees. It is in the area known as West Lathrop, which was annexed to the City of Lathrop in 1997. Stewart Tract is an island in the Sacramento-San Joaquin River Delta bounded by the San Joaquin River on the north and east, Old River on the west, and Paradise Cut on the south. Union Pacific Railroad (UPRR) tracks are located along the eastern boundary of the largest portion of the project site. Paradise Cut is used for irrigation and as a flood control bypass channel carrying flood waters from the San Joaquin River to Old River. The area adjacent to the project site is largely agricultural. However, the

Mossdale portion of West Lathrop immediately north of the project is currently undergoing urban development. Developed portions of the City of Lathrop are east of Interstate Highway 5 and the proposed project site.

The proposed project area covers approximately 4,905 acres of Stewart Tract, which flooded in 1997, and surrounding waterways. The project would include work in the San Joaquin River, Old River, Paradise Cut, an unnamed drainage channel, pond and adjacent wetlands on Stewart Tract, for the purpose of rebuilding and strengthening existing levees, constructing a series of setback levees, and constructing residential and commercial development, including recreation facilities, back bays and an interior lake. Excavation and expansion of Paradise Cut would be undertaken to increase its storage and flow capacity. Levees along Old River and the San Joaquin River would be reconfigured and strengthened by the addition of soil on the landward side of the levees to create high-ground corridors along the river edges. A new cross-levee would be build immediately west of, and paralleling, the existing UPRR right-of-way. The applicant asserts levee work along the San Joaquin River and Old River afford the opportunity for back bays which would create limited flood control storage, habitat for various Delta fisheries and sites for recreational facilities, including marinas.

Under the applicant's proposed alternative, approximately 11,000 homes, five million square feet of commercial and retail space and a variety of other community facilities and associated infrastructure would be constructed. The mixed-use development would cover approximately 4,115 acres and include a town center district, an employment center, public service facilities, retail and commercial uses, residential neighborhoods, lakes and water features, schools, parks and trails, golf courses, open space and habitat areas. Two bridge crossings over the San Joaquin River and two bridge crossings over Paradise Cut would be constructed to provide access to and from the developed areas. Water-oriented recreational facilities would include boat docks, ramps and piers. Docks sufficient to provide 921 total berths would be constructed. The applicant also proposes to create approximately 280 acres of open water habitat and 35 acres of wetlands in the central lake.

A Subsequent Environmental Impact Report (EIR) for the River Islands at Lathrop Project was certified by the City of Lathrop in January, 2003. A General Plan Amendment, West Lathrop Specific Plan amendment, rezoning and an Urban Design Concept have also been approved by the City.

A delineation which identifies approximately 379 acres of waters of the United States, including 41.18 acres of emergent wetlands, 55.23 acres of scrub/shrub wetlands, 60.92 acres of forested wetlands, 2.77 acres of pond, and 218.51 acres of riverine/channel aquatic habitat, within the approximately 5,546-acre area surveyed for the project site, was verified by the Corps on January 30, 2004. The applicant asserts that approximately 32-acres of waters, including wetlands, would be lost to project construction under their preferred alternative. The proposed project would also directly and indirectly impact other waters, including wetlands, in and around the project.

The applicant's proposed conceptual mitigation for the project's impacts to waters consists of creation of approximately 140 acres of new waters in Paradise Cut and approximately 85 acres of new waters in the proposed back bays. These would include approximately 46 acres of emergent wetland and shallow water habitat (less than 10-feet deep) for various fish species and restoration of approximately 10 acres of wetlands at the Paradise Weir bench.

The proposed project may affect federally-listed endangered or threatened species or their critical habitat including delta smelt, steelhead, spring-run chinook salmon, winter-run chinook salmon, giant garter snake, riparian brush rabbit, and valley elderberry longhorn beetle. Other special status species may occur in the project area. The proposed project may adversely affect Essential Fish Habitat (EFH) as defined in the Magnuson-Stevens Fishery Conservation and Management Act. Once a biological assessment has been completed, the Corps will initiate formal consultation with the U.S. Fish and Wildlife Service and NOAA Fisheries, under Section 7 of the Endangered Species Act, for federally-listed threatened or endangered species and for EFH that would be affected by the project. The Corps will also consult with the State Historic Preservation Officer under Section 106 of the National Historic Preservation Act for properties listed or potentially eligible for listing on the National Register of Historic Places, as appropriate.

A number of on-site and off-site project alternatives, including the no-action alternative, will be evaluated in the DEIS in accordance with NEPA and the Section 404(b)(1) guidelines.

Potentially significant issues to be analyzed in depth in the DEIS include, but are not limited to, wetlands and terrestrial biology, cultural resources, water quality, hydrology and flood protection, floodplain management, navigation, agricultural resources, transportation and traffic and air quality.

The above determinations are based on information provided by the applicant and upon the Corps' preliminary review. The Corps is soliciting verbal and written comments from the public, Federal, State and local agencies and officials, Indian tribes, and other interested parties in order to consider and evaluate the impacts of this proposed activity. The Corps' public involvement program includes several opportunities to provide oral and written comments. Affected Federal, State, local agencies, Indian tribes, and other interested private organizations and the general public are invited to participate.

Dated: May 31, 2005.

Ronald N. Light,

Colonel, Corps of Engineers, District Engineer.

[FR Doc. 05–11499 Filed 6–9–05; 8:45 am]

BILLING CODE 3710–EH–M

DEPARTMENT OF EDUCATION

Notice of Proposed Information Collection Requests

AGENCY: Department of Education.

SUMMARY: The Leader, Information Management Case Services Team, Regulatory Information Management Services, Office of the Chief Information Officer, invites comments on the proposed information collection requests as required by the Paperwork Reduction Act of 1995.

DATES: Interested persons are invited to submit comments on or before August 9, 2005.

SUPPLEMENTARY INFORMATION: Section 3506 of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35) requires that the Office of Management and Budget (OMB) provide interested Federal agencies and the public an early opportunity to comment on information collection requests. OMB may amend or waive the requirement for public consultation to the extent that public participation in the approval process would defeat the purpose of the information collection, violate State or Federal law, or substantially interfere with any agency's ability to perform its statutory obligations. The Leader,

Information Management Case Services Team, Regulatory Information Management Services, Office of the Chief Information Officer, publishes that notice containing proposed information collection requests prior to submission of these requests to OMB. Each proposed information collection, grouped by office, contains the following: (1) Type of review requested, *e.g.* new, revision, extension, existing or reinstatement; (2) title; (3) summary of the collection; (4) description of the need for, and proposed use of, the information; (5) respondents and frequency of collection; and (6) reporting and/or recordkeeping burden. OMB invites public comment.

The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology.

Dated: June 6, 2005.

Angela C. Arrington,

Leader, Information Management Case Services Team, Regulatory Information Management Services, Office of the Chief Information Officer.

Office of Vocational and Adult Education

Type of Review: Reinstatement.

Title: Adult Education Annual Performance and Financial Reports.

Frequency: Annually.

Affected Public: State, local, or tribal gov't, SEAs or LEAs.

Reporting and Recordkeeping Hour Burden:

Responses: 57.

Burden Hours: 5,700.

Abstract: The information contained in the Annual Performance Reports for Adult Education is needed to monitor the performance of the activities and services funded under the Adult Education and Family Literacy Act of 1998, Report to Congress on the Levels of Performance Achieved on the core indicators of performance, provide necessary outcome information to meet OVAE's Government Performance and Results Act (GPRA) goals for adult education, and provide documentation for incentive awards under Title V of the Workforce Investment Act. The respondents include eligible agencies in 59 states and insular areas.

Requests for copies of the proposed information collection request may be accessed from *http://edicsweb.ed.gov,* by selecting the ''Browse Pending Collections'' link and by clicking on link number 2794. When you access the information collection, click on ''Download Attachments'' to view. Written requests for information should be addressed to U.S. Department of Education, 400 Maryland Avenue, SW., Potomac Center, 9th Floor, Washington, DC 20202–4700. Requests may also be electronically mailed to the Internet address *OCIO_RIMG@ed.gov* or faxed to 202–245–6621. Please specify the complete title of the information collection when making your request.

Comments regarding burden and/or the collection activity requirements should be directed to Sheila Carey at her e-mail address *Sheila.Carey@ed.gov.* Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339.

[FR Doc. 05–11484 Filed 6–9–05; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Office of Science; Fusion Energy Sciences Advisory Committee

AGENCY: Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: This notice announces a meeting of the Fusion Energy Sciences Advisory Committee. The Federal Advisory Committee Act (Pub. L. 92–463, 86 Stat. 770) requires that public notice of these meetings be announced in the **Federal Register**.

DATES: Tuesday, July 19, 2005, 8 a.m.–6 p.m.

Wednesday, July 20, 2005, 8 a.m.–12 noon.

ADDRESSES: The Marriott Hotel, 9751 Washingtonian Boulevard, Gaithersburg, MD 20878.

FOR FURTHER INFORMATION CONTACT: Albert L. Opdenaker, Office of Fusion Energy Sciences; U.S. Department of Energy;1000 Independence Avenue, SW., Washington, DC 20585–1290; Telephone: (301) 903–4927.

SUPPLEMENTARY INFORMATION:

Purpose of the Meeting: The major purpose of the meeting is for the full Committee to respond to the report from its panel on fusion facilities.

Tentative Agenda

Tuesday, July 19, 2005—

- Office of Science Perspective.
- Office of Fusion Energy Sciences Perspective.
- Presentation by the Fusion Facilities Panel on its findings and recommendations.
- Public Comments.

Wednesday, July 20, 2005—

- Prepare letter to DOE transmitting the facilities panel report.
- Adjourn.

Public Participation: The meeting is open to the public. If you would like to file a written statement with the Committee, you may do so either before or after the meeting. If you would like to make oral statements regarding any of the items on the agenda, you should contact Albert L. Opdenaker at 301–903–8584 (fax) or *albert.opdenaker@science.doe.gov* (e-mail). You must make your request for an oral statement at least 5 business days before the meeting. Reasonable provision will be made to include the scheduled oral statements on the agenda. The Chairperson of the Committee will conduct the meeting to facilitate the orderly conduct of business. Public comment will follow the 10-minute rule.

Minutes: We will make the minutes of this meeting available for public review and copying within 30 days at the Freedom of Information Public Reading Room; IE–190; Forrestal Building; 1000 Independence Avenue, SW., Washington, DC, between 9 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

Issued at Washington, DC, on June 6, 2005.

Rachel Samuel,

Deputy Committee Management Officer.

[FR Doc. 05–11529 Filed 6–9–05; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. IC05–550–001, FERC–550]

Commission Information Collection Activities, Proposed Collection; Comment Request; Submitted for OMB Review

May 31, 2005.

AGENCY: Federal Energy Regulatory Commission.

ACTION: Notice.

SUMMARY: In compliance with the requirements of section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. 3507, the Federal Energy Regulatory Commission (Commission) has submitted the information

collection described below to the Office of Management and Budget (OMB) for review of this information collection requirement. Any interested person may file comments directly with OMB and should address a copy of those comments to the Commission as explained below. The Commission received one comment in response to an earlier **Federal Register** notice of March 1, 2005 (70 FR 9938–39), and has prepared a response to the commenter in its submission to OMB.

DATES: Comments on the collection of information are due by June 30, 2005.

ADDRESSES: Address comments on the collection of information to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention: Federal Energy Regulatory Commission Desk Officer. Comments to OMB should be filed electronically, c/o *oira_submission@omb.eop.gov* and include the OMB Control No. as a point of reference. The Desk Officer may be reached by telephone at 202–395–4650. A copy of the comments should also be sent to the Federal Energy Regulatory Commission, Office of the Executive Director, ED–33, Attention: Michael Miller, 888 First Street, NE., Washington, DC 20426. Comments may be filed either in paper format or electronically. Those persons filing electronically do not need to make a paper filing. For paper filings, such comments should be submitted to the Office of the Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426 and should refer to Docket No. IC05–550–001.

Documents filed electronically via the Internet must be prepared in, MS Word, Portable Document Format, Word Perfect or ASCII format. To file the document, access the Commission's Web site at *http://www.ferc.gov* and click on ''Make an E-filing,'' and then follow the instructions for each screen. First time users will have to establish a user name and password. The Commission will send an automatic acknowledgment to the sender's e-mail address upon receipt of comments. User assistance for electronic filings is available at 202–502–8258 or by e-mail to *efiling@ferc.gov*. Comments should not be submitted to the e-mail address.

All comments are available for review at the Commission or may be viewed on the Commission's Web site at *http://www.ferc.gov*, using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll-free at (866) 208–3676, or for TTY, contact (202) 502–8659.

FOR FURTHER INFORMATION CONTACT: Michael Miller may be reached by telephone at (202) 502–8415, by fax at (202) 273–0873, and by e-mail at *michael.miller@ferc.gov*.

SUPPLEMENTARY INFORMATION:

Description

The information collection submitted for OMB review contains the following:

1. *Collection of Information:* FERC–550 ''Oil Pipeline Rates: Tariff Filings''

2. *Sponsor:* Federal Energy Regulatory Commission.

3. *Control No.:* 1902–0089.

The Commission is now requesting that OMB approve with a three-year extension of the expiration date, with no changes to the existing collection. The information filed with the Commission is mandatory.

4. *Necessity of the Collection of Information:* The filing requirement provides the basis for analysis of all rates, fares, or charges whatsoever demanded, charged or collected by any common carrier or carriers in connection with the transportation of crude oil and petroleum products and is used by the Commission for determining the just and reasonable rates that should be charged by the regulated pipeline company. Based on this analysis, a recommendation is made to the Commission to take action whether to suspend, accept or reject the proposed rate. The data required to be filed for pipeline rates and tariff filings is specified by 18 Code of Federal Regulations (CFR) Chapter I, parts 340–348.

Jurisdiction over oil pipelines as it relates to the establishment of rates or charges for the transportation of oil by pipeline or the establishment or valuations for pipelines, was transferred from the Interstate Commerce Commission (ICC) to FERC, pursuant to sections 306 and 402 of the Department of Energy Organization Act (DOE Act).

5. *Respondent Description:* The respondent universe currently comprises on average 200 respondents subject to the Commission's jurisdiction. The Commission estimates that it will receive annually on average 3 filings per year per respondent.

6. *Estimated Burden:* 6,600 total hours, 200 respondents (average per year), 3 responses per respondent, and 11 hours per response (average).

7. *Estimated Cost Burden to respondents:* The estimated total cost to respondents is $344,463. (6,600 hours ÷ 2080 hours per year × $108,558)

Statutory Authority: Part I, Sections 1, 6, and 15 of the Interstate Commerce Act (ICA), (Pub. L. 337, 34 Stat. 384.) Sections 306 and 402 of the Department of Energy Organization Act, 42 U.S.C. 7155 and 7172, and Executive Order No. 12009.

Magalie R. Salas,

Secretary.

[FR Doc. E5–2994 Filed 6–9–05; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket Nos. ER98–3809–000, et al.]

3E Technologies, Inc.. et al.; Notice of Institution of Proceeding and Refund Effective Date

June 1, 2005.

In the matter of: ER98–3809–000, ER97–2867–000, ER99–2369–000, ER98–4685–000, ER00–3109–001, ER00–105–000, ER03–770–000, ER02–1084–000, ER96–1818–000, ER97–512–000, ER00–861–000, ER96–1145–000, ER01–1758–000, ER00–2823–000, ER97–464–000, ER97–2045–000, ER99–2792–000, ER98–3378–000, ER97–2132–000, ER01–2355–000, ER00–679–000, ER98–1821–000, ER02–246–000, ER97–886–000, ER98–4515–000, ER98–701–000, ER01–1701–000, ER02–246–000, ER01–2692–000, ER00–2945–000, ER01–2138–000, ER01–1183–000, ER01–390–000, ER96–2640–000, ER90–225–000, ER99–964–000, ER00–2187–000, ER97–1968–000, ER05–737–000, ER90–24–000, ER02–246–000, ER01–1836–000, ER98–1790–000, ER01–2562–000, ER02–1118–000, ER96–1410–000, ER01–544–000, ER96–2624–000, ER01–138–000, ER01–2071–000, ER02–1866–000, ER94–1161–000, ER99–2774–000, ER94–1099–000, ER99–3098–000, ER94–1478–000, ER98–2020–000, ER03–1294–000, ER98–2918–000, ER96–358–000, ER01–2221–000, ER00–874–000, ER96–138–000, ER99–2061–000, ER99–254–000, ER01–1166–000, ER96–2964–000, ER98–3233–000, ER01–2439–000, ER01–666–000, ER97–382–000, ER00–3039–000, ER96–918–000, ER00–1258–000, ER97–3580–000, ER99–2454–000, ER02–687–000, ER00–2706–000, ER00–2392–001, ER02–1173–000, ER96–795–000, ER96–1933–000, ER01–1078–000, ER01–2405–000, ER98–4334–000, ER02–1600–000, ER98–2535–000, ER01–1760–000, ER02–1366–000, ER01–3023–000, ER01–2129–000, ER96–1819–000, ER01–2395–000, ER95–802–000, ER98–3478–000, ER00–1519–000, ER94–6–000, ER01–688–000, ER00–2306–000, ER95–784–000, ER95–295–000, ER95–232–000, ER03–1259–000, ER95–1018–000, ER97–2904–000, ER94–1672–000, ER99–3554–000, ER02–30–000, ER96–1947–000, ER01–1507–000, ER00–1781–000, ER98–1992–000, ER99–801–000, ER01–95–000, ER99–1156–000, ER95–78–000, ER96–2027–000, ER99–1293–000, ER96–2143–000, ER01–2509–000, ER01–1336–002, ER02–1238–000, ER97–610–000, ER95–1278–000, ER95–1374–000, ER94–1593–000, ER95–192–000, ER01–352–

000, ER98–2618–000, ER99–2537–000, ER97–2681–000, ER96–1122–000, ER96–2892–000, ER96–2585–000, ER98–1915–000, ER00–795–000, ER01–2224–000, ER00–774–000, ER94–152–000, ER02–245–000, ER97–1716–000, ER01–904–000, ER98–622–000, ER02–41–000, ER98–3048–000, ER98–1125–000, ER01–1479–000, ER02–845–000, ER97–181–000, ER01–2783–000, ER99–2883–000, ER97–18–000, ER95–379–000, ER03–372–000, ER98–3719–000, ER02–417–000, ER01–1821–000, ER95–72–000, ER99–3275–000, ER96–2303–000, ER97–3187–000, ER96–1–000, ER98–4333–000, ER01–2463–000, ER95–968–000, ER99–4380–000, ER99–1876–000, ER96–404–000, ER00–23–000, ER02–809–000, ER01–2760–000, ER96–1516–000, ER01–1121–000, ER99–2109–000, ER98–2603–000, ER95–362–000, ER01–542–000, ER98–4643–000, ER99–1228–000, ER96–3107–000, ER00–167–000, ER96–2591–000, ER97–870–000, ER01–2217–002, ER96–2524–000, ER00–1250–000, ER95–581–000, ER95–1787–000, ER97–4185–000, ER01–2694–000, ER99–3571–000, ER96–2241–000, ER02–298–000, ER01–373–000, ER00–494–000, ER98–3184–000, ER98–1055–000, ER96–1316–000, ER01–3148–000, ER95–692–000, ER98–564–000, ER01–2234–000, ER97–3428–000, ER04–957–000, ER96–105–000, ER96–3092–000, ER93–3–000, ER01–1709–000, ER02–1046–000, ER96–2830–000, ER98–537–000, ER00–1928–000 and EL05–111–000; AC Power Corporation, ACES Power Marketing LLC, ACN Power, Inc., Adirondack Hydro Development Corporation, AI Energy, Inc., AIG Energy Inc., Alcan Power Marketing Inc., Alliance Power Marketing, Inc., A'Lones Group, Inc., Alrus Consulting, LLC, Alternate Power Source, Inc., Altorfer Inc., American Cooperative Services, Inc., Amvest Coal Sales, Inc., Amvest Power, Inc., Archer Daniels Midland Company, Astra Power, LLC, Atlantic Energy Technologies, Inc., Beacon Generating, LLC, Black River Power, LLC, Bollinger Energy Corporation, Boston Edison Company, Brooklyn Navy Yard Cogeneration Partners, LP, Cadillac Renewable Energy LLC, California Polar Power Broker, L.L.C., Callaway Golf Company, Cambridge Electric Light Company, Canastota Windpower, LLC, Candela Energy Corporation, Capital Energy, Inc., Celerity Energy of New Mexico, LLC, Chandler Wind Partners, Inc., CHI Power Marketing, Inc., Chicago Electric Trading, L.L.C., Cielo Power Market, L.P., CMS Distributed Power, L.L.C., Colonial Energy, Inc., Commerce Energy Inc., Commonwealth Atlantic L.P., Commonwealth Electric Company, Community Energy, Inc., Competisys LLC, Competitive Energy Services, LLC, Continental Electric Cooperative Services, Inc., Cook Inlet Energy Supply L.P., Cook Inlet Power, LP, Cumberland Power, Inc., Delta Person Limited Partnership, Desert Power, L.P., Desert Southwest Power, LLC, Direct Electric Inc., Duke Energy Trading and Marketing, L.L.C., Eclipse Energy, Inc., EGC 1999 Holding Company, L.P., Electrade Corporation, Energy Clearinghouse Corp., Energy Cooperative of New York, Inc., Energy PM, Inc., Energy Resource Management Corp., Energy Transfer-Hanover Ventures, LP, Energy West Resources, Inc., EnergyOnline, Inc., Enjet, Inc., ENMAR Corporation, Enron Sandhill Limited Partnership, Enserco Energy Inc., Environmental Resources Trust, Inc., Equitec Power, LLC, EWO Marketing, L.P., Exact Power Co., Inc., Exeter Energy Limited Partnership, Federal Energy Sales, Inc., First Electric Cooperative Corporation, First Power, LLC, Florida Keys Electric Cooperative Association, Inc., FMF Energy, Inc., Foote Creek IV, LLC, Fresno Cogeneration Partners, L.P., Front Range Power Company, LLC, Gateway Energy Marketing, Gelber Group, Inc., George Colliers, Inc., GNA Energy, LLC, Golden Valley Power Company, Green Mountain Energy Company, Hafslund Energy Trading LLC, Haleywest L.L.C., Hess Energy Power & Gas Company, LLC, Hinson Power Company, LLC, Holt Company of Ohio, ICC Energy Corporation, IDACORP Energy, LP, IEP Power Marketing, LLC, INFINERGY Services, LLC, InPower Marketing Corporation, InterCoast Power Marketing Company, IPP Energy LLC, It's Electric & Gas, L.L.C., J. Anthony & Associates Ltd, Kaztex Energy Ventures, Inc., Kimball Power Company, Kloco Corporation, Kohler Company, Lake Benton Power Partners, LLC, Lambda Energy Marketing Company, Lone Star Steel Sales Company, Longhorn Power, LP, LS Power Marketing, LLC, Lumberton Power, LLC, Marquette Energy, LLC, Medical Area Total Energy Plant, Inc., Metro Energy Group, LLC, Miami Valley Lighting, Inc., Michigan Gas Exchange, L.L.C., Mid-American Resources, Inc., Midwest Energy, Inc., Monmouth Energy, Inc., Monterey Consulting Associates, Inc, Morrow Power, LLC, Mountainview Power Partners II, LLC, MPC Generating, LLC, Murphy Oil USA, Inc., NAP Trading and Marketing, Inc., National Fuel Resources, Inc., National Power Exchange Corp., National Power Management Company, Natural Gas Trading Corporation, Nautilus Energy Company, Navitas, Inc., New Millennium Energy Corp., NFR Power, Inc., NGTS Energy Services, Niagara Mohawk Power Corp., Nine Energy Services, LLC, Nordic Electric, L.L.C., Nordic Energy Barge 1 & 2, L.L.C., Nordic Marketing, L.L.C., North American Energy Conservation, Inc., North American Energy, L.L.C., North Atlantic Utilities Inc., North Carolina Power Holdings, LLC, North Star Power Marketing, LLC, North Western Energy Marketing, LLC, Northeast Electricity Inc., Northeast Empire L.P. #2, Northwest Regional Power, LLC, Northwestern Wind Power, LLC, Oceanside Energy, Inc., ODEC Power Trading, Inc., Old Mill Power Company, P&T Power Company, Peak Energy, Inc., Peak Power Generating Company, People's Electric Corp., Phoenix Wind Power LLC, Power Dynamics, Inc., Power Exchange Corporation, Power Management Co., LLC, Power Providers Inc., Power Systems Group, Inc., Powertec International, LLC, Primary Power Marketing, L.L.C., Pro-Energy Development LLC, Progas Power Inc., Proliance Energy, L.L.C., PS Energy Group, Inc., Questar Energy Trading Company, Rayburn Country Electric Cooperative, Inc., Renewable Energy Resources LLC, Ridge Crest Wind Partners, LLC, SEMCOR Energy, SF Phosphates Limited Company, LLC, Shell Energy Services Company, LLC, Southwood 2000, Inc., Stand Energy Corporation, STI Capital Company, Storm Lake Power Partners I, LLC, Storm Lake Power Partners II LLC, Strategic Energy LLC, Strategic Energy Management Corp., Strategic Power Management, Inc., Sunoco Power Marketing, L.L.C., Sunrise Power Company, Symmetry Device Research, Inc., Tacoma Energy Recovery Company, Tennessee Power Company, Texaco Natural Gas Inc., Texas-New Mexico Power Co., The Energy Group of America, Inc., The Legacy Energy Group, LLC, Thicksten Grimm Burgum, Inc., Thompson River Co-Gen, LLC, Tiger Natural Gas, Inc., TransAlta Centralia Generation LLC, TransAlta Energy Marketing (CA) Inc., TransAlta Energy Marketing (US) Inc., TransAlta Energy Marketing Corp., TransAlta Energy Marketing Corp. (US), TransCanada Energy Ltd., TransCanada Power Marketing Ltd., Travis Energy & Environment, Inc., Tri-Valley Corporation, TXU Electric Delivery Company, U.S. Power & Light, Inc., United American Energy Corp., United Illuminating Company, VIASYN, Inc., Walton County Power, LLC, Washington Gas Energy Services, Inc., Western Energy Marketers, Inc. and Western New York Wind Corporation; Notice of Institution of Proceeding and Refund Effective Date.

On May 31, 2005, the Commission issued an order that instituted a proceeding in Docket No. EL05–111–000, pursuant to section 206 of the Federal Power Act (FPA), 16 U.S.C. 824e, concerning the justness and reasonableness of the market-based rates of the above-captioned sellers. *3E Technologies, Inc., et al.*, 111 FERC ¶ 61,295 (2005).

The refund effective date in Docket No. EL05–111–000, established pursuant to section 206(b) of the FPA, will be 60 days from the date of publication of this notice in the **Federal Register**.

Magalie R. Salas,

Secretary.

[FR Doc. E5–2990 Filed 6–9–05; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP99–301–132]

ANR Pipeline Company; Notice of Negotiated Rate Filing

June 1, 2005.

Take notice that on May 24, 2005, ANR Pipeline Company (ANR) tendered for filing and approval amendments to two previously approved negotiated rate service agreements, and one new negotiated rate agreement, entered into between ANR and Wisconsin Electric Power Company (WEPCO), pursuant to ANR's Rate Schedules FTS–3 and NNS. ANR states that this filing also includes

a new short-term maximum rate FTS–1 Agreement, as well as a discounted and amended short-term FTS–3 Agreement.

ANR requests that the Commission accept and approve the subject negotiated rate amendments/agreements to be effective in accordance with each agreement's respective term.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). 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 notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed in accordance with the provisions of Section 154.210 of the Commission's regulations (18 CFR 154.210). Anyone filing an intervention or protest must serve a copy of that document on the Applicant. Anyone filing an intervention or protest on or before the intervention or protest date need not serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov*. Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov*, using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov*, or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Magalie R. Salas,

Secretary.

[FR Doc. E5–2989 Filed 6–9–05; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP96–200–142]

CenterPoint Energy Gas Transmission Company; Notice of Tariff Filing

June 1, 2005.

Take notice that on May 26, 2005, CenterPoint Energy Gas Transmission Company (CEGT) tendered for filing as part of its FERC Gas Tariff, Sixth Revised Volume No. 1, First Revised Sheet No. 854, to be effective November 1, 2004.

CEGT states that the purpose of this filing is to reflect the expiration of a negotiated rate transaction.

Any person desiring to protest this filing must file in accordance with Rule 211 of the Commission's Rules of Practice and Procedure (18 CFR 385.211). Protests to this filing 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. Such protests must be filed in accordance with the provisions of Section 154.210 of the Commission's regulations (18 CFR 154.210). Anyone filing a protest must serve a copy of that document on all the parties to the proceeding.

The Commission encourages electronic submission of protests in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov*. Persons unable to file electronically should submit an original and 14 copies of the protest to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov*, using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov*, or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Magalie R. Salas,

Secretary.

[FR Doc. E5–3007 Filed 6–9–05; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket Nos. ER05–816–000, ER05–817–000, ER05–818–000, ER05–819–000 and ER05–820–000]

CES Marketing VI, LLC, CES Marketing VII, LLC, CES Marketing VIIII, LLC, CES Marketing IX, LLC and CES Marketing X, LLC; Notice of Issuance of Order

June 1, 2005.

CES Marketing VI, LLC, CES Marketing VII, LLC, CES Marketing VIII, LLC, CES Marketing IX, LLC, CES Marketing X, LLC (together, CESM VI–X) filed applications for market-based rate authority, with accompanying tariffs. The proposed rate tariff provides for wholesale sales of energy, capacity and ancillary services at market-based rates. CESM VI–X also requested waiver of various Commission regulations. In particular, CESM VI–X requested that the Commission grant blanket approval under 18 CFR part 34 of all future issuances of securities and assumptions of liability by CESM VI–X.

On May 26, 2005, the Commission granted the request for blanket approval under part 34, subject to the following:

Any person desiring to be heard or to protest the blanket approval of issuances of securities or assumptions of liability by CESM VI–X should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure. 18 CFR 385.211, 385.214 (2004).

Notice is hereby given that the deadline for filing motions to intervene or protest, is June 27, 2005.

Absent a request to be heard in opposition by the deadline above, CESM VI–X is authorized to issue securities and assume obligations or liabilities as a guarantor, indorser, surety, or otherwise in respect of any security of another person; provided that CESM VI–X, compatible with the public interest, and is reasonably necessary or appropriate for such purposes.

The Commission reserves the right to require a further showing that neither public nor private interests will be adversely affected by continued approval of CESM VI–X's issuances of securities or assumptions of liability.

Copies of the full text of the Commission's Order are available from the Commission's Public Reference Room, 888 First Street, NE., Washington, DC 20426. The Order may also be viewed on the Commission's

Web site at *http:www.ferc.gov*, using the eLibrary link. Enter the docket number excluding the last three digits in the docket number filed to access the document. Comments, protests, and interventions may be filed electronically via the Internet in lieu of paper. *See* 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the ''e-Filing'' link. The Commission strongly encourages electronic filings.

Magalie R. Salas,

Secretary.

[FR Doc. E5–2992 Filed 6–9–05; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket Nos. ER05–725–000 and ER05–725–001]

Deephaven RV Sub Fund Ltd.; Notice of Issuance of Order

June 1, 2005.

Deephaven RV Sub Fund Ltd. (Deephaven) filed an application for market-based rate authority, with an accompanying tariff. The proposed rate tariff provides for wholesale sales of energy, capacity and ancillary services at market-based rates. Deephaven also requested waiver of various Commission regulations. In particular, Deephaven requested that the Commission grant blanket approval under 18 CFR part 34 of all future issuances of securities and assumptions of liability by Deephaven.

On May 26, 2005, the Commission granted the request for blanket approval under part 34, subject to the following:

Any person desiring to be heard or to protest the blanket approval of issuances of securities or assumptions of liability by Deephaven should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure. 18 CFR 385.211, 385.214 (2004).

Notice is hereby given that the deadline for filing motions to intervene or protest, is June 27, 2005.

Absent a request to be heard in opposition by the deadline above, Deephaven is authorized to issue securities and assume obligations or liabilities as a guarantor, indorser, surety, or otherwise in respect of any security of another person; provided that Deephaven, compatible with the public interest, and is reasonably necessary or appropriate for such purposes.

The Commission reserves the right to require a further showing that neither public nor private interests will be adversely affected by continued approval of Deephaven's issuances of securities or assumptions of liability.

Copies of the full text of the Commission's Order are available from the Commission's Public Reference Room, 888 First Street, NE., Washington, DC 20426. The Order may also be viewed on the Commission's Web site at *http://www.ferc.gov*, using the eLibrary link. Enter the docket number excluding the last three digits in the docket number filed to access the document. Comments, protests, and interventions may be filed electronically via the internet in lieu of paper. *See* 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the ''e-Filing'' link. The Commission strongly encourages electronic filings.

Magalie R. Salas,

Secretary.

[FR Doc. E5–2991 Filed 6–9–05; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP05–51–001]

Dominion Transmission, Inc.; Notice of Compliance Filing

June 1, 2005.

Take notice that on May 26, 2005, Dominion Transmission, Inc. (DTI) submitted a compliance filing pursuant to the Federal Energy Regulatory Commission's Order on technical conference issued on April 29, 2005 in the captioned docket.

DTI states that copies of the filing were served on parties on the official service list in the above-captioned proceeding.

Any person desiring to protest this filing must file in accordance with Rule 211 of the Commission's Rules of Practice and Procedure (18 CFR 385.211). Protests to this filing 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. Such protests must be filed in accordance with the provisions of Section 154.210 of the Commission's regulations (18 CFR 154.210). Anyone filing a protest must serve a copy of that document on all the parties to the proceeding.

The Commission encourages electronic submission of protests in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov*. Persons unable to file electronically should submit an original and 14 copies of the protest to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov*, using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov*, or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Magalie R. Salas,

Secretary.

[FR Doc. E5–3006 Filed 6–9–05; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ES05–30–000]

El Paso Electric Company; Notice of Application

May 31, 2005.

Take notice that on May 25, 2005, El Paso Electric Company (El Paso) submitted an application pursuant to section 204 of the Federal Power Act seeking authorization to undertake certain transactions and assume obligations associated with the refinancing of pollution control bonds (PCBs) issued for the benefit of El Paso.

El Paso also requests a waiver from the Commission's competitive bidding and negotiated placement requirements at 18 CFR 34.2.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). 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 notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the

comment date. Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant. On or before the comment date, it is not necessary to serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov*. Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov*, using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov*, or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5 p.m. eastern time on June 17, 2005.

Magalie R. Salas,

Secretary.

[FR Doc. E5–2993 Filed 6–9–05; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2496–103]

Eugene Water and Electric Board; Notice Dismissing Request for Rehearing as Moot

June 1, 2005.

On August 23, 2004, the Eugene Water and Electric Board (Electric Board) filed a motion requesting an extension of time to comply with Articles 412 and 413 of the license for the Leaburg-Walterville Project No. 2496, which require filing plans to augment spawning gravel downstream of Leaburg dam and enhance fish habitat, respectively. On September 20, 2004, Commission staff issued an order granting the Electric Board's request. On October 18, 2004, the Oregon Department of Fish and Wildlife (Oregon DFW) filed a request for rehearing of the September 20 Order.

On November 1, 2004, Oregon DFW's request for rehearing of the September 20, 2004 Order was rejected by notice because Oregon DFW was not a party to the extension of time proceeding.[1] On November 26, 2004, Oregon DFW filed a request for rehearing of the November 1 notice.[2]

On February 2, 2005, the Electric Board filed the gravel augmentation and fish habitat enhancement plans. By order issued on March 15, 2005, the Commission modified and approved the plans.[3] Since both of the plans in question have been filed and approved, and no rehearing requests were filed on the Commission's March 15 Order, Oregon DFW's request for rehearing of the November 1, 2004 notice and the accompanying notice of intervention are moot. Accordingly, the Electric Board's request for rehearing of the November 1, 2004 notice and the accompanying notice of intervention dismissed as moot.

This notice constitutes final agency action. Request for rehearing by the Commission of this notice must be filed within 30 days of the date of issuance of this notice, pursuant to 18 CFR 385.713.

Magalie R. Salas,

Secretary.

[FR Doc. E5–2998 Filed 6–9–05; 8:45 am]

BILLING CODE 6717–01–P

[1] Oregon DFW was not a party because it had not filed a notice of intervention.

[2] Oregon DFW's request for rehearing was accompanied by a notice of intervention.

[3] *Eugene Water and Electric Board* 110 FERC ¶ 62,263 (2005).

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP05–355–000]

Gas Transmission Northwest Corporation; Notice of Proposed Changes in FERC Gas Tariff

June 1, 2005.

Take notice that on May 26, 2005, Gas Transmission Northwest Corporation (GTN) tendered for filing as part of its FERC Gas Tariff, Third Revised Volume No. 1–A, Second Revised Sheet No. 117, to become effective June 27, 2005.

GTN states that this tariff sheet is being submitted to add tariff language that will allow GTN, at a shipper's request, to incur third party charges for the benefit of the shipper and to bill the shipper for such charges.

GTN further states that a copy of this filing has been served on GTN's jurisdictional customers and interested State regulatory agencies.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). 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 notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed in accordance with the provisions of Section 154.210 of the Commission's regulations (18 CFR 154.210). Anyone filing an intervention or protest must serve a copy of that document on the Applicant. Anyone filing an intervention or protest on or before the intervention or protest date need not serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Magalie R. Salas,

Secretary.

[FR Doc. E5–3002 Filed 6–9–05; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP05–356–000]

North Baja Pipeline, LLC; Notice of Proposed Changes in FERC Gas Tariff

June 1, 2005.

Take notice that on May 26, 2005, North Baja Pipeline, LLC (NBP) tendered for filing as part of its FERC Gas Tariff, Original Volume No. 1,

Second Revised Sheet No. 114, to become effective June 27, 2005.

NBP states that this tariff sheet is being submitted to add tariff language that will allow NBP, at a shipper's request, to incur third party charges for the benefit of the shipper and to bill the shipper for such charges.

NBP further states that a copy of this filing has been served on NBP's jurisdictional customers and interested State regulatory agencies.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). 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 notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed in accordance with the provisions of Section 154.210 of the Commission's regulations (18 CFR 154.210). Anyone filing an intervention or protest must serve a copy of that document on the Applicant. Anyone filing an intervention or protest on or before the intervention or protest date need not serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Magalie R. Salas,

Secretary.

[FR Doc. E5–3003 Filed 6–9–05; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. PR05–8–000]

Northwest Natural Gas Company; Notice of Filing of Stipulation and Agreement and Dates for Comments and Reply Comments

June 1, 2005.

Take notice that on May 27, 2005, Northwest Natural Gas Company (NW Natural) filed a stipulation and agreement and offer of settlement in the above-captioned proceeding to resolve all issues arising out of NW Natural's January 18, 2005, petition for rate approval regarding proposed rates for firm and interruptible storage and related transportation services made pursuant to sections 284.224 and 284.123(b)(2) of the Commission's regulations. NW Natural states that the filing is offered as a comprehensive resolution of all of the issues in the referenced proceeding.

Any person desiring to comment in this proceeding should file initial comments with the Federal Energy Regulatory Commission on or before June 3, 2005. Reply comments must be filed on or before June 8, 2005.

Magalie R. Salas,

Secretary.

[FR Doc. E5–3001 Filed 6–9–05; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP05–357–000]

Young Gas Storage Company, Ltd.; Notice of Proposed Changes in FERC Gas Tariff

June 1, 2005.

Take notice that on May 27, 2005, Young Gas Storage Company, Ltd. (Young) tendered for filing as part of its FERC Gas Tariff, Original Volume No. 1, Tenth Revised Sheet No. 52 to become effective June 27, 2005.

Young states that the tariff sheet provides shippers with the flexibility to exceed the Reservoir Integrity Inventory Limit when operationally feasible.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). 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 notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed in accordance with the provisions of Section 154.210 of the Commission's regulations (18 CFR 154.210). Anyone filing an intervention or protest must serve a copy of that document on the Applicant. Anyone filing an intervention or protest on or before the intervention or protest date need not serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov*. Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov*, using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov*, or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Magalie R. Salas,

Secretary.

[FR Doc. E5–3004 Filed 6–9–05; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP05–92–000]

Liberty Gas Storage, L.L.C.; Notice of Extension of Scoping Period Closing Date

June 1, 2005.

On May 18, 2005, the Commission issued a ''Notice of Intent To Prepare an Environmental Assessment for the Proposed Liberty Gas Storage Project and Request for Comments on Environmental Issues'' in the above-captioned proceeding. The subsequent mailing of this notice was incomplete and did not reach all of the intended parties.

The notice has been mailed again to all affected parties. The scoping period closing date is hereby extended to June 29, 2005.

Magalie R. Salas,

Secretary.

[FR Doc. E5–3008 Filed 6–9–05; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Application Accepting for Filing and Soliciting Motions To Intervene, Protests and Comments

June 1, 2005.

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Type of Application:* Preliminary permit.

b. *Project No.:* 12579–000.

c. *Date filed:* March 14, 2005.

d. *Applicant:* Alaska Power & Telephone Company.

e. *Name of Project:* Boundary Lake Hydroelectric Project.

f. *Location:* On Boundary Creek and Boundary Lake, near the City of Juneau, Borough of Juneau, Alaska, within the Tongass National Forest.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791(a)—825(r).

h. *Applicant Contact:* Mr. Robert S. Grimm, President, Alaska Power & Telephone Company, P.O. Box 3222, Port Townsend, WA 98368, (360) 385–1733 x 120.

i. *FERC Contact:* Etta Foster, (202) 502–8769.

j. *Deadline for filing comments, protests, and motions to intervene:* 60 days from the issuance date of this notice.

All documents (original and eight copies) should be filed with Magalie R. Salas, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426. Please include the project number (P–12579–000) on any comments, protests, or motions filed.

k. *Description of Project:* The proposed project would consist of: (1) A proposed concrete, steel, or wood crib diversion and intake structure approximately 45-feet-high and 100-feet-long on Boundary Lake and Boundary Creek; (2) a reservoir with a surface area of 50 acres and a storage capacity of 5,000 acre-feet at an elevation of 900 feet; (3) a low-pressure pipe penstock approximately 1,800 feet in length and 60-inches in diameter; (4) a powerhouse containing 1 or 2 turbines to achieve the maximum capacity for generation of 9 megawatts; (5) a tailrace that will extend a short distance to the Taku River; (6) a 35 kV transmission line that is 0.4 miles long, and (7) appurtenant facilities.

The project would have an annual generation of 35(GWh) gigawatt-hours.

l. *Location of Application:* A copy of the application is available for inspection and reproduction at the Commission in the Public Reference Room, located at 888 First Street, NE., Room 2A, Washington, DC 20426, or by calling (202) 502–8371. This filing may also be viewed on the Commission's Web site at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, call toll-free 1–866–208–3676 or e-mail *FERCOnlineSupport@ferc.gov.* For TTY, call (202) 502–8659. A copy is also available for inspection and reproduction at the address in item h. above.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

n. *Competing Preliminary Permit*—Anyone desiring to file a competing application for preliminary permit for a proposed project must submit the competing application itself, or a notice of intent to file such an application, to the Commission on or before the specified comment date for the particular application (*see* 18 CFR 4.36). Submission of a timely notice of intent allows an interested person to file the competing preliminary permit application no later than 30 days after the specified comment date for the particular application. A competing preliminary permit application must conform with 18 CFR 4.30(b) and 4.36.

o. *Competing Development Application*—Any qualified development applicant desiring to file a competing development application must submit to the Commission, on or before a specified comment date for the particular application, either a competing development application or a notice of intent to file such an application. Submission of a timely notice of intent to file a development application allows an interested person to file the competing application no later than 120 days after the specified comment date for the particular application. A competing license application must conform with 18 CFR 4.30(b) and 4.36.

p. *Notice of Intent*—a notice of intent must specify the exact name, business address, and telephone number of the prospective applicant, and must include an unequivocal statement of intent to submit, if such an application may be filed, either a preliminary permit application or a development application (specify which type of application). A notice of intent must be served on the applicant(s) named in this public notice.

q. *Proposed Scope of Studies Under Permit*—A preliminary permit, if issued, does not authorize construction. The term of the proposed preliminary permit would be 36 months. The work proposed under the preliminary permit would include economic analysis, preparation of preliminary engineering plans, and a study of environmental impacts. Based on the results of these studies, the Applicant would decide whether to proceed with the preparation of a development application to construct and operate the project.

r. *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.

Comments, protests and interventions may be filed electronically via the Internet in lieu of paper; *see* 18 CFR 385.2001 (a)(1)(iii) and the instructions on the Commission's Web site under ''e-filing'' link. The Commission strongly encourages electronic filing.

s. *Filing and Service of Responsive Documents*—Any filings must bear in all capital letter 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, NE., Washington, DC 20426. A copy of any motion to intervene must also be served upon each representative of the Applicant specified in the particular application.

t. *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.

Magalie R. Salas,

Secretary.

[FR Doc. E5–2995 Filed 6–9–05; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Application Accepted for Filing and Soliciting Comments, Protests, and Motions To Intervene

June 1, 2005.

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Type of Application:* Preliminary permit.

b. *Project No.:* 12586–000.

c. *Date filed:* April 27, 2005.

d. *Applicant:* Paradise Irrigation District.

e. *Name and Location of Project:* The proposed Paradise Hydroelectric Project would be located in Butte County in California and would occupy lands administered by the Bureau of Land Management and the U.S. Forest Service.

f. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791(a)—825(r).

g. *Applicant contact:* Mr. George Barber, District Manager, Paradise Irrigation District, 5325 Black Olive Drive, P.O. Box 2409, Paradise, CA 95967–4971, (530) 877–4971.

h. *FERC Contact:* Tom Papsidero, (202) 502–6002.

i. *Deadline for filing comments, protests, and motions to intervene:* 60 days from the issuance date of this notice.

All documents (original and eight copies) should be filed with Magalie R. Salas, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426. Comments, protests and interventions may be filed electronically via the Internet in lieu of paper; *see* 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the ''e-Filing'' link. The Commission strongly encourages electronic filings. Please include the project number (P–12586–000) on any comments or motions filed.

The Commission's Rules of Practice and Procedure require all intervenors filing documents with the Commission to serve a copy of that document on each person in the official service list for the project. Further, if an intervenor files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

j. *Description of Existing Facilities and Proposed Project:* The proposed project would use the applicant's existing 175-foot-high, 975-foot-long Paradise Dam and Reservoir, which occupies approximately 90 acres of Federal land, and which has a storage capacity of 11,500 acre-feet, a surface area of 244 acres, and normal maximum surface elevation of 2,568 feet msl. The applicant proposes to study several alternatives at the site and the proposed project would likely consist of: (1) A new powerhouse to be located on Federal land, containing one turbine-generator unit with a total installed capacity of 350 kW; (2) a new 30-inch-wide steel penstock (3) a new 0.5-mile-long transmission line; and (4) appurtenant facilities. The proposed project would have an annual generation of 1,091 MWh.

k. *Location of Applications:* A copy of the application is available for inspection and reproduction at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, call toll-free 1–866–208–3676 or e-mail *FERCOnlineSupport@ferc.gov.* For TTY, call (202) 502–8659. A copy is also available for inspection and reproduction at the address in item g above.

l. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

m. *Competing Preliminary Permit*—Anyone desiring to file a competing application for preliminary permit for a proposed project must submit the competing application itself, or a notice of intent to file such an application, to the Commission on or before the specified comment date for the particular application (*see* 18 CFR 4.36). Submission of a timely notice of intent allows an interested person to file the competing preliminary permit application no later than 30 days after the specified comment date for the particular application. A competing preliminary permit application must conform with 18 CFR 4.30(b) and 4.36.

m. *Competing Development Application*—Any qualified development applicant desiring to file a competing development application must submit to the Commission, on or before a specified comment date for the particular application, either a competing development application or a notice of intent to file such an application. Submission of a timely notice of intent to file a development application allows an interested person to file the competing application no later than 120 days after the specified comment date for the particular application. A competing license application must conform with 18 CFR 4.30(b) and 4.36.

n. *Notice of Intent*—A notice of intent must specify the exact name, business address, and telephone number of the prospective applicant, and must include an unequivocal statement of intent to submit, if such an application may be filed, either a preliminary permit application or a development application (specify which type of application). A notice of intent must be served on the applicant(s) named in this public notice.

o. *Proposed Scope of Studies Under Permit*—A preliminary permit, if issued, does not authorize construction. The term of the proposed preliminary permit would be 36 months. The work proposed under the preliminary permit would include economic analysis, preparation of preliminary engineering plans, and a study of environmental impacts. Based on the results of these studies, the Applicant would decide whether to proceed with the preparation of a development application to construct and operate the project.

p. *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.

Comments, protests and interventions may be filed electronically via the

Internet in lieu of paper; *see* 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under ''e-filing'' link. The Commission strongly encourages electronic filing.

q. *Filing and Service of Responsive Documents*—Any filings must bear in all capital letters the title ''COMMENTS'', ''NOTICE OF INTENT TO FILE COMPETING APPLICATION'', ''COMPETING APPLICATION'', ''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, NE., Washington, DC 20426. An additional copy must be sent to Director, Division of Hydropower Administration and Compliance, Federal Energy Regulatory Commission, at the above-mentioned address. A copy of any notice of intent, competing application or motion to intervene must also be served upon each representative of the Applicant specified in the particular application.

r. *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.

Magalie R. Salas,

Secretary.

[FR Doc. E5–2996 Filed 6–9–05; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Application for Transfer of License and Approval of Financing Arrangement and Soliciting Comments, Motions To Intervene, and Protests

June 1, 2005.

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Application Type:* Motion to substitute transferor in transfer of license.

b. *Project No.:* 1855–030.

c. *Date Filed:* May 24, 2005.

d. *Applicants:* USGen New England, Inc. (USGenNE); TransCanada Hydro Northeast Inc. (TC Hydro NE); Town of Rockingham, Vermont (Town); Bellows Falls Power Company, LLC (BFPC); Vermont Hydro-Electric Power Authority (VHPA).

e. *Name and Location of Project:* Bellows Falls, P–1855: Connecticut River in Windham and Windsor Counties, Vermont and Cheshire and Sullivan Counties, New Hampshire.

f. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791a—825r.

g. *Applicants' Contact:* Amy S. Koch, Patton Boggs LLP, 2550 M Street, NW., Washington, DC 20037, (202) 457–6000.

h. *FERC Contact:* James Hunter at (202) 502–6086.

i. *Deadline for filing comments, protests, and motions to intervene:* July 1, 2005.

All documents (original and eight copies) should be filed with: Magalie R. Salas, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426. Comments, protests, and interventions may be filed electronically via the Internet in lieu of paper; *see* 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the ''e-Filing'' link. The Commission strongly encourages electronic filings. Please include the Project Number on any comments or motions filed.

The Commission's Rules of Practice and Procedure require all intervenors filing a document with the Commission to serve a copy of that document on each person in the official service list for the project. Further, if an intervenor files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the documents on that resource agency.

j. *Description of Application:* As described in the notice issued February 7, 2005, USGenNE, the Town, BFPC, and VHPA sought Commission approval to transfer the license for the Bellows Falls Project from USGenNE to the Town and BFPC as co-licensees and for approval of a financing plan under Standard Article 5 whereby VHPA would, at closing, take title to project property and transfer it to the Town. This transfer was requested as an alternative, for this project only, to the transfer from USGenNE to TC Hydro NE of this project and four others that was approved by order issued on January 24, 2005, but not, at that time, consummated. The Applicants now report that TC Hydro NE purchased the Bellows Falls Project from USGenNE on April 1, 2005, and request that TC Hydro NE be substituted for USGenNE as the transferor in the current proceeding.

k. This filing is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at *http://www.ferc.gov* using the ''FERRIS'' link. Enter the docket number (P–1855) in the docket number field to access the document. For assistance, call toll-free 1–866–208–3676 or e-mail *FERCOnlineSupport@ferc.gov*. For TTY, call (202) 502–8659. A copy is also available for inspection and reproduction at the addresses in item g. above.

l. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

m. *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.

n. *Filing and Service of Responsive Documents*—Any filings must bear in all capital letters the title ''COMMENTS'', ''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 eight copies to: The Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426. A copy of any motion to intervene must also be served upon each representative of the Applicants specified in the particular application.

o. *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 Applicants. 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 Applicants' representatives.

Magalie R. Salas,

Secretary.

[FR Doc. E5–2997 Filed 6–9–05; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2738–054]

New York State Electric & Gas Corporation; Notice of Application Ready for Environmental Analysis and Soliciting Comments, Recommendations, Terms and Conditions, and Prescriptions

June 1, 2005.

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection.

a. *Type of Application:* New major license.

b. *Project No.:* P–2738–054.

c. *Date filed:* April 5, 2004.

d. *Applicant:* New York State Electric & Gas Corporation.

e. *Name of Project:* Saranac River Hydroelectric Project.

f. *Location:* On the Saranac River, in Clinton County, New York. This project does not occupy Federal lands.

g. *Filed Pursuant to:* Federal Power Act 16 U.S.C. 791 (a)–825(r).

h. *Applicant Contact:* Hugh Ives, New York State Electric & Gas Corporation, Corporate Drive, Kirkwood Industrial Park, P.O. Box 5224, Binghamton, NY 13902, (585) 724–8209.

i. *FERC Contact:* Tom Dean, (202) 502–6041 or *thomas.dean@ferc.gov.*

j. Deadline for filing comments, recommendations, terms and conditions, and prescriptions is 60 days from the issuance date of this notice; reply comments are due 105 days from the issuance date of this notice.

All documents (original and eight copies) should be filed with: Magalie R. Salas, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

The Commission's Rules of Practice require all intervenors filing documents with the Commission to serve a copy of that document on each person on the official service list for the project. Further, if an intervenor files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

Comments, recommendations, terms and conditions, and prescriptions may be filed electronically via the Internet in lieu of paper. The Commission strongly encourages electronic filings. *See* 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site (*http://www.ferc.gov*) under the ''eFiling'' link.

k. This application has been accepted, and is ready for environmental analysis at this time.

l. *Project Description:* The project consists of the following four developments:

The High Falls Development consists of the following existing facilities:

(1) A 63-foot-high, 274-foot-long concrete gravity dam with spillway topped with 5-foot-high flashboards; (2) a 110-foot-long eastern wingwall and a 320-foot-long western wingwall; (3) a 46-acre reservoir; (4) an 800-foot-long, 19-foot-wide forebay canal; (5) an 11-foot by 12-foot, 3,581-foot-long tunnel; (6) a 10-foot-diameter, 1,280-foot-long penstock; (7) three 6-foot-diameter, 150-foot-long penstocks; (8) a 30-foot-diameter surge tank; (9) a powerhouse containing three generating units with a total installed capacity of 15,000 kW; (10) a 50-foot-long, 6.9-kV transmission line; and (11) other appurtenances.

The Cadyville Development consists of the following existing facilities: (1) A 50-foot-high, 237-foot-long concrete gravity dam with spillway topped with 2.7-foot-high flashboards; (2) a 200-acre reservoir; (3) a 58-foot-long, 20-foot-wide intake; (4) a 10-foot-diameter, 1,554-foot-long penstock; (5) a powerhouse containing three generating units with a total installed capacity of 5,525 kW; (6) a 110-foot-long, 6.6-kV transmission line; and (7) other appurtenances.

The Mill C Development consists of the following existing facilities: (1) A 43-foot-high, 202-foot-long stone masonry dam with spillway topped with 2-foot-high flashboards; (2) a 7.9-acre reservoir; (3) a 37-foot-long, 18-foot-wide intake; (4) a 11.5-foot to 10-foot-diameter, 494-foot-long penstock; (5) a 11.1-foot to 10-foot-diameter, 84-foot-long penstocks; (6) one powerhouse containing two generating units with a total installed capacity of 2,250 kW; (7) another powerhouse containing a single generating unit with an installed capacity of 3,800 kW; (8) a 700-foot-long, 6.6-kV transmission line; and (9) other appurtenances.

The Kents Falls Development consists of the following existing facilities: (1) A 59-foot-high, 172-foot-long concrete gravity dam with spillway topped with 3.5-foot-high flashboards; (2) a 34-acre reservoir; (3) a 29-foot-long, 22-foot-wide intake; (4) an 11-foot-diameter, 2,652-foot-long penstock; (5) three 6-foot-diameter, 16-foot-long penstocks; (6) a 28-foot-diameter surge tank; (7) a powerhouse containing two generating units with a total installed capacity of 12,400 kW; (8) a 390-foot-long, 6.6-kV transmission line; and (9) other appurtenances.

The license applicant filed a settlement agreement on January 3, 2005, that contain provisions to change project operation and measures for aquatic and recreation resources.

m. A copy of the application is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll-free at 1–866–208–3676, or for TTY, (202) 502–8659. A copy is also available for inspection and reproduction at the address in item h above.

All filings must (1) bear in all capital letters the title ''COMMENTS'', ''REPLY COMMENTS'', ''RECOMMENDATIONS,'' ''TERMS AND CONDITIONS,'' or ''PRESCRIPTIONS;'' (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person submitting the filing; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, recommendations, terms and conditions or prescriptions must set forth their evidentiary basis and otherwise comply with the requirements of 18 CFR 4.34(b). Agencies may obtain copies of the application directly from the applicant. Each filing must be accompanied by proof of service on all persons listed on the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 4.34(b), and 385.2010.

n. You may also register online at *http://www.ferc.gov.esubscribenow.htm* to be notified via e-mail of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

o. Procedural schedule and final amendments: The application will be processed according to the following Hydro Licensing Schedule. Revisions to the schedule will be made as appropriate. The Commission staff proposes to issue one environmental assessment rather than issue a draft and

final EA. Comments, terms and conditions, recommendations, prescriptions, and reply comments, if any, will be addressed in an EA. Staff intends to give at least 30 days for entities to comment on the EA, and will take into consideration all comments received on the EA before final action is taken on the license application.

Notice of the availability of the EA: October 2005.

Ready for Commission decision on the application: December 2005.

Final amendments to the application must be filed with the Commission no later than 30 days from the issuance date of the notice of ready for environmental analysis.

Magalie R. Salas,

Secretary.

[FR Doc. E5–2999 Filed 6–9–05; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Application for Amendment of License and Soliciting Comments, Motions To Intervene, and Protests

June 1, 2005.

Take notice that the following application has been filed with the Commission and is available for public inspection:

a. *Application Type:* Amendment of license.

b. *Project Nos.:* 4204–038, 4659–042, and 4660–043.

c. *Date Filed:* April 18, 2005.

d. *Applicants:* City of Batesville, and Independence County, Arkansas.

e. *Name of Project:* Lock and Dam Nos. 1, 2 and 3 (White River Project).

f. *Location:* The project is located on the White River, Independence and Stone counties, Arkansas.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791a–825r.

h. *Applicant Contact:* Mr. Donald H. Clarke, Counsel, Law Offices of GKRSE, 1500 K Street, NW., Suite 330, Washington, DC 20005, tel. (202) 408–5400, Fax (202) 408–5406.

i. *FERC Contact:* Any questions on this notice should be addressed to Mrs. Anumzziatta Purchiaroni at (202) 502–6191, or e-mail address: *anumzziatta.purchiaroni@ferc.gov.*

j. *Deadline for filing comments and or motions:* July 1, 2005.

k. *Description of Request:* The applicants filed for Commission's approval revised Exhibit G drawings for each of the three projects. The drawings reflect revised boundaries for the White River Project Transmission Line. The applicants indicate in the filing that the changes constitute adjustments to the transmission line, which were necessary based on actual field conditions, property owner requests, and avoidance of archeological sites.

l. *Locations of the Application:* A copy of the application is available for inspection and reproduction at the Commission's Public Reference Room, located at 888 First Street, NE., Room 2A, Washington, DC 20426, or by calling (202) 502–8371. Information about this filing may also be viewed on the Commission's Web site at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via e-mail of new filings and issuances related to this or other pending projects. For assistance, call 1–866–208–3676 or e-mail *FERCOnlineSupport@ferc.gov*, for TTY, call (202) 502–8659. A copy is also available for inspection and reproduction at the address in item (h) above.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

n. *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.

o. *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. All documents (original and eight copies) should be filed with: Magalie R. Salas, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington DC 20426. A copy of any motion to intervene must also be served upon each representative of the Applicant specified in the particular application.

p. *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.

q. Comments, protests and interventions may be filed electronically via the Internet in lieu of paper. *See* 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site at *http://www.ferc.gov* under the ''e-Filing'' link.

Linda L. Mitry,

Deputy Secretary.

[FR Doc. E5–3012 Filed 6–9–05; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[OEI–2005–0003, OEI–2005–0004, FRL–7923–1]

Agency Information Collection Activities: Proposed Collection; Comment Request; Background Checks for Contractor Employees (Renewal), EPA ICR Number 2159.02, OMB Control Number 2030–0043; Proposed Collection; Comment Request; Drug Testing for Contract Employees (Renewal), EPA ICR Number 2183.02, OMB Control Number 2030–0044

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), this document announces that EPA is planning to submit two continuing Information Collection Requests (ICRs) to the Office of Management and Budget (OMB). This is a request to renew two existing approved collections. These ICRs are scheduled to expire on 09/30/05. Before submitting the ICRs to OMB for review and approval, EPA is soliciting comments on specific aspects of the proposed information collection as described below.

DATES: Comments must be submitted on or before August 9, 2005.

ADDRESSES: Submit your comments, referencing docket ID number OEI–2005–0003 for Background Checks for

Contractor Employees (Renewal), EPA ICR Number 2159.02, OMB Control Number 2030–0043, and OEI–2005–0004 for Drug Testing for Contract Employees (Renewal), EPA ICR Number 2183.02, OMB Control Number 2030–0044, to EPA online using EDOCKET (our preferred method), by e-mail to *oei.docket@epa.gov*, or by mail to: EPA Docket Center (28221T), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

FOR FURTHER INFORMATION CONTACT: Paul Schaffer, U.S. EPA, Office of Acquisition Management, Mail Code (3802R), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (202) 564–4366; fax number: (202) 565–2475; e-mail address: *schaffer.paul@epa.gov.*

SUPPLEMENTARY INFORMATION: EPA has established a public docket for these ICR's under Docket ID number OEI–2005–0003 for Background Checks for Contractor Employees (Renewal), EPA ICR Number 2159.02, OMB Control Number 2030–0043, and OEI–2005–0004 for Drug Testing for Contract Employees (Renewal), EPA ICR Number 2183.02, OMB Control Number 2030–0044, which is available for public viewing in the EPA Docket Center (EPA/DC), EPA West, Room B102, 1301 Constitution Ave., NW., Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Reading Room is (202) 566–1744, and the telephone number for the OEI Docket is (202) 566–1752. An electronic version of the public docket is available through EPA Dockets (EDOCKET) at *http://www.epa.gov/edocket.* Use EDOCKET to obtain a copy of the draft collection of information, submit or view public comments, access the index listing of the contents of the public docket, and to access those documents in the public docket that are available electronically. Once in the system, select ''search,'' then key in the docket ID number identified above.

Any comments related to these ICR should be submitted to EPA within 60 days of this notice. EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in EDOCKET as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose public disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EDOCKET. The entire printed comment, including the copyrighted material, will be available in the public docket. Although identified as an item in the official docket, information claimed as CBI, or whose disclosure is otherwise restricted by statute, is not included in the official public docket, and will not be available for public viewing in EDOCKET. For further information about the electronic docket, see EPA's **Federal Register** notice describing the electronic docket at 67 FR 38102 (May 31, 2002), or go to *http://www.epa.gov/edocket.*

Affected entities: Entities potentially affected by this action are contractors performing work at sensitive sites or on sensitive projects, and not covered under the provisions of Homeland Security Presidential Directive -12. Specifically, all contractors involved with Emergency Response, Superfund, Information Systems, Facility Services, and Research Support that have significant security concerns, as determined by the Contracting Officer on a case-by-case basis, will be required to provide qualified personnel that meet the background check and drug testing requirements developed by EPA.

Titles: Background Checks for Contractor Employees (Renewal); Drug Testing for Contractor Employees (Renewal).

Abstract: Background checks cover citizenship or valid visa, criminal convictions, weapons offenses, felony convictions, parties prohibited from receiving federal contracts. Drug tests are for the presence of marijuana, cocaine, opiates, amphetamines and phencyclidine (PCP). The Contractor shall maintain records of all background checks and drug tests. An agency 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 OMB control numbers for EPA's regulations in 40 CFR are listed in 40 CFR part 9.

The EPA would like to solicit comments to:

(i) Evaluate 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) Evaluate 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) Enhance the quality, utility, and clarity of the information to be collected; and

(iv) Minimize 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 submission of responses.

Burden Statement: The number of contractor employees expected to submit the requested information for background checks is 3,000 for the life of this ICR (3 years) or 1,000 occurrences per year. The number of annual occurrences, 1,000, multiplied by the respondent burden effort of 1 hour to collect information, equals a total of 1,000 hours per year. The total annual respondent cost for performing background checks collection requests is $179,000. This is calculated by multiplying the number of annual occurrences, 1,000, by the respondent cost of one collection, $179.

The number of contractor employees expected to submit the requested information for drug testing is 450 occurrences per year. The number of annual occurrences, 450, multiplied by the respondent burden effort of 1 hour to collect information, equals a total of 450 hours per year. The total annual respondent cost for this collection request is $65,250. This is calculated by multiplying the number of occurrences, 450, by the cost of one collection, $145.

Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

Dated: June 6, 2005.

John C. Gherardini,

Acting Director, Office of Acquisition Management.

[FR Doc. 05–11545 Filed 6–9–05; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–7923–6]

Request for Nominations to the Good Neighbor Environmental Board

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of request for nominations.

SUMMARY: The U.S. Environmental Protection Agency invites nominations of qualified candidates to be considered for appointments to fill several vacancies on the Good Neighbor Environmental Board. The Board advises the President and Congress on environmental and infrastructure issues along the United States border with Mexico. It is managed by EPA.

For this round of recruitment, given the nature of current vacancies, and given the goal of maintaining diverse representation across geographic locations and sectors, those meeting the following criteria are especially encouraged to apply: (1) Individuals living in the U.S. border states of Texas and New Mexico, particularly border communities, who (2) have experience and expertise in either local or county government; the academic sector; or the private sector. Other individuals with other types of expertise living in the other two U.S. border states also are welcome to apply for membership. Individuals may apply themselves, or be nominated. Letters of reference are encouraged.

In addition, from the federal agency contingent of the Board, senior officials from the following departments have, or will be, ending their terms shortly, and successors will be appointed: Department of Health and Human Services; Department of the Interior; and the Environmental Protection Agency.

The deadline for receiving applications for membership is August 15. All appointments will be made by the Administrator of EPA. The announcement of new appointments is scheduled for early October 2005, in advance of the Board's next meeting, which will take place on October 17–19, 2005, on Tohono O'odham Nation land near Tucson, Arizona.

ADDRESSES: Submit application materials to Elaine Koerner, Designated Federal Officer, Good Neighbor Environmental Board, Mail Code 1601 E, U.S. Environmental Protection Agency, 655 15th St., NW., Suite 800, Washington, DC 20460. T: 202–233–0069; F: 202–233–0070. *koerner.elaine@epa.gov.*

FOR FURTHER INFORMATION CONTACT: Elaine Koerner, Designated Federal Officer, Good Neighbor Environmental Board, EPA Region 9 Office, WTR–4, 75 Hawthorne St., San Francisco, CA 94105, T: 415–972–3437, F: 415–947–3537, e-mail *koerner.elaine@epa.gov.*

SUPPLEMENTARY INFORMATION: The Good Neighbor Environmental Board meets three times each calendar year; locations include Washington, DC and various locations along the U.S.-Mexico border. It was created by the Enterprise for the Americas Initiative Act of 1992. An Executive Order delegates implementing authority to the Administrator of EPA. The Board is responsible for providing advice to the U.S. President and Congress on environmental and infrastructure issues and needs within the States contiguous to Mexico in order to improve the quality of life of persons residing on the U.S. side of the border. The statute calls for the Board to have representatives from U.S. Government agencies; the governments of the States of Arizona, California, New Mexico and Texas; and private organizations with expertise on environmental and infrastructure problems along the southwest border. Board members typically contribute 10–15 hours per month to the Board's work. The Board membership position is voluntary; travel expenses are covered.

The following criteria will be used to evaluate nominees:

- Residence in one of the four U.S. border states.
- Professional knowledge of, and experience with, environmental infrastructure activities and policy along the U.S.-Mexico border.
- Senior level-experience that fills a gap in Board representation, or brings a new and relevant dimension to its deliberations.
- Representation of a sector or group that is involved in border region environmental infrastructure.
- Demonstrated ability to work in a consensus-building process with a wide range of representatives from diverse constituencies.
- Willingness to serve a two-year term as an actively-contributing member, with possible re-appointment to a second term.

Nominees' qualifications will be assessed under the mandates of the Federal Advisory Committee Act, which requires Committees to maintain diversity across a broad range of constituencies, sectors, and groups.

Nominations for membership must include a resume describing the professional and educational qualifications of the nominee as well as community-based experience. Contact details should include full name and title, business mailing address, telephone, fax, and e-mail address. A supporting letter of endorsement is encouraged but not required.

Dated: May 22, 2005.

Elaine M. Koerner,

Designated Federal Officer.

[FR Doc. 05–11542 Filed 6–9–05; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–6664–3])

Environmental Impact Statements and Regulations; Availability of EPA Comments

Availability of EPA comments prepared 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 1, 2005 (70 FR 16815).

Draft EISs

EIS No. 20050139, ERP No. D–COE–G32058–00, Arkansas River Navigation Study, To Maintain and Improve the Navigation Channel in Order to Enhance Commercial Navigation on the McCellan Kerr Arkansas River Navigation System (MKARNS), Several Counties, AR and Several Counties, OK.

Summary: EPA expressed environmental concerns due to wetland and aquatic resource impacts, and mitigation related to these impacts.

Rating EC2.

EIS No. 20050141, ERP No. D–USA–E11056–FL, Eglin Air Force Base and Hurlburt Field Military Family Housing, Demolition, Construction, Renovation and Leasing (DCR&L) Program, Okaloosa County, FL.

Summary: EPA expressed concern related to alternatives, best management practices to reduce impacts from polluted stormwater run-off, and sensitive areas/species.

Rating EC2.

EIS No. 20050120, ERP No. DS–AFS–J65327–CO, Baylor Park Blowdown Project, New Information, Salvage and Treat Down and Damaged Timber, To Reduce Impact of Spruce Beetles,

Implementation, White River National Forest, Sopris and Rifle Ranger Districts, Garfield, Mesa and Pitkin Counties, CO.

Summary: EPA has no objection to the proposed action.

Rating LO.

Final EISs

EIS No. 20050167, ERP No. F–AFS–D65049–WV, Fernow Experimental Forest, To Continue Long-Term Research and Initiate New Research, Involving Removal of Trees, Prescribed Burning, Stem Injection of Selected of Trees, Control Invasive Plant Species, Northeastern Research Station, Parson, Tucker County, WV.

Summary: The Forest Service has adequately addressed EPA's previous comments, therefore, EPA has no objection to the proposed action.

Dated: June 7, 2005.

Ken Mittelholtz,

Environmental Protection Specialist, Office of Federal Activities.

[FR Doc. 05–11555 Filed 6–9–05; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–6664–2]

Environmental Impacts Statements; Notice of Availability

Responsible Agency: Office of Federal Activities, General Information (202) 564–7167 or *http://www.epa.gov/compliance/nepa/.*

Weekly receipt of Environmental Impact Statements.

Filed 05/30/2005 Through 06/03/2005.

Pursuant to 40 CFR 1506.9.

EIS No. 20050218, Final EIS, NPS, OR, Crater Lake National Park General Management Plan, Implementation, Klamath, Jackson and Douglas Counties, OR, Wait Period Ends: 07/05/2005, Contact: Terry Urbanowski 303–969–2277

EIS No. 20050219, Final EIS, BLM, 00, California Coastal National Monument Resource Management Plan, To Protect Important Biological and Geological Values: Islands, Rocks, Exposed Reefs, and Pinnacles above Mean High Tide, CA, OR and Mexico, Wait Period Ends: 07/11/2005, Contact: Brenda Williams 202–452–5112.

EIS No. 20050220, Draft EIS, FHW, WA, Interstate 90 Snoqualmie Pass East Project, Proposes to Improve a 15-mile Portion of I–90 from Milepost 55.10 in Hyak to Milepost 70.3 New Easton, Funding, U.S. Army COE Section 404 Permit and NPDES Permit, Kittitas County, WA, Comment Period Ends: 08/05/2005, Contact: Steve Saxton 360–753–9556 This document is available on the Internet at: *http://www.wsdot.wa.gov/projects/I90/SomqualmiePassEast/.*

EIS No. 20050221, Draft EIS, FHW, VA, Southeastern Parkway and Greenbelt Location Study, Construction from Chesapeake and Virginia Beach, Funding and U.S. Army COE Section 404 Permit, Cities of Chesapeake and Virginia Beach, VA, Comment Period Ends: 07/25/2005, Contact: Ken Myers 804–775–3353.

EIS No. 20050222, Draft EIS, FAA, AZ, Phoenix Sky Harbor International Airport (PHX), Construction and Operation of a Terminal, Airfield and Surface Transportation, City of Phoenix, Maricopa County, AZ, Comment Period Ends: 07/26/2005, Contact: Jennifer Mendelsohn 310–725–3637

EIS No. 20050223, Final EIS, FHW, UT, 11400 South Project, Proposed Improvement to the Transportation Network in the Southern Salt Lake Valley from 12300/12600 South to 10400/10600 South, and from Bangerter Highway to 700 East, Salt Lake City, Salt Lake County, UT, wait period ends: 07/11/2005 Contact: Jeff Berna 801–963–0078 ext 235.

EIS No. 20050224, Final Supplement, FHW, NY, NY–9A Reconstruction Project, West Thames Street to Chambers Street in Lower Manhattan the Result of September 11, 2001 Attack, Lower Manhattan Redevelopment, New York County, NY, Wait Period Ends: 07/11/2005, Contact: Richard Schmalz 212–267–4113.

EIS No. 20050225, Final EIS, HUD, NY, Ridge Hill Village Project, Construction, Comprehensive Development Plan, (CDP), Planned Mixed-Use Developmental District (PMD), U.S. Army COE Section 404 Permit, City of Yonkers, Westchester County, NY, Wait Period Ends: 07/11/2005, Contact: Joan Deierlein 914–377–6015.

EIS No. 20050226, Draft EIS, FHW, RI, U.S. Route 6/Route 10 Interchange Improvement Project, To Identify Transportation Alternative, Funding, City of Providence, Providence County, RI, Comment Period Ends: 08/01/2005, Contact: Ralph Rizzo 401–528–4548.

EIS No. 20050227, Final EIS, COE, 00, Lower Snake River Navigation Maintenance, To Perform Routine Maintenance of the Federal Navigation Channel and Berthing Areas, Lower Snake and Clearwater Rivers, WA and ID, Wait Period Ends: 07/11/2005, Contact: Jack Sands 509–527–7287. This document is available on the Internet at: *http://www.nww.usace.army.mil/channel/_maint/one-yeardefault.htm.*

EIS No. 20050228, Draft EIS, FHW, VA, U.S. 460 Location Study Project, Transportation Improvements from I–295 in Prince George County to the Interchange of Route 460 and 58 along the Suffolk Bypass, Funding, U.S. Army COE Section 10 and 404 Permits, Prince George, Sussex, Surry, Southampton and Isle of Wight Counties, VA, Comment Period Ends: 07/25/2005, Contact: Ken Myers 804–775–3358

EIS No. 20050229, Draft EIS, AFS, OR, Blue Mountain Land Exchange—Oregon Project, Proposed Exchange of Federal and Non-Federal Lands, Malheur, Umatilla, and Wallowa-Whitman National Forests, Baker, Grant, Morrow, Umatilla, Union and Wallowa Counties, OR, Comment Period Ends: 07/25/2005, Contact: Jean Lavell 541–523–1230.

EIS No. 20050230, Final EIS, FRC, 00, Golden Pass Liquefied Natural Gas (LNG) Import Terminal and Natural Gas Pipeline Facilities, Construction and Operation, Jefferson, Orange, Newton Counties, TX and Calcasieu Parish, LA, Wait Period Ends: 07/11/2005, Contact: Thomas Russo 1–866–208–3372.

Amended Notices

EIS No. 20050133, Draft EIS, AFS, OH, Wayne National Forest, Proposed Revised Land and Resource Management Plan, Implementation, Several Counties, OH, Due: 07/01/2005, Contact: Bob Gianniny 770–753–0101 Revision of FR Notice Published on 04/01/2005: CEQ Comment Period Ending on 6/30/2005 has been Extended to 07/01/2005.

EIS No. 20050176, Draft EIS, FAA, AK, Juneau International Airport, Proposed Development Activities to Enhance Operations Safety, Facilitate Aircraft Alignment, US Army COE Section 404 Permit, City and Borough of Juneau, AK, Comment Period Ends: 06/30/2005, Contact: Patti Sullivan 907–271–5454 Revision of FR Notice Published on 05/06/2005: Correction to Review Period Ending 06/20/2005 to 06/30/2005.

EIS No. 20050202, Draft EIS, CGD, 00, Programmatic—Vessel and Facility Response Plans for Oil: 2003 Removal Equipment Requirements and Alternative Technology Revisions, To Increase the Oil Removal Capability, U.S. Exclusive Economic Zone (EEZ), United States, Alaska, Guam, Puerto

Pico and other U.S. Territories, Comment Period Ends: 08/01/2005, Contact: Brad McKitrick 202–267–0995 Revision of FR Notice Published on 05/27/2005: Correction to CEQ Comment Period Ending 07/26 /2005 has been Extended to 08/01/2005.

EIS No. 20050209, Draft EIS, NPS, WY, Grand Teton National Park Transportation Plan, Implementation, Grand Teton National Park, Teton County, WY, Comment Period Ends: 08/01/2005, Contact: Adrienne Anderson 303–987–6730 Revision of FR Notice Published on 06/03/2005: Correction to Comment Period Ending 07/18/2005 to 08/01/2005.

Dated: June 7, 2005.

Ken Mittelholtz,

Environmental Protection Specialist, Office of Federal Activities.

[FR Doc. 05–11557 Filed 6–9–05; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisition of Shares of Bank 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 office 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 June 24, 2005.

A. Federal Reserve Bank of Chicago (Patrick M. Wilder, Assistant Vice President) 230 South LaSalle Street, Chicago, Illinois 60690-1414:

1. Marjorie E. Binder, Chicago, Illinois; to acquire additional voting shares of Bellwood Bancorporation, Inc., Bellwood, Illinois, and thereby indirectly acquire voting shares of Greater Chicago Bank, Bellwood, Illinois.

Board of Governors of the Federal Reserve System, June 6, 2005.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 05–11527 Filed 6–9–05; 8:45 am]

BILLING CODE 6210–01–S

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 (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States. Additional information on all bank holding companies may be obtained from the National Information Center website at *www.ffiec.gov/nic/*.

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 July 5, 2005.

A. Federal Reserve Bank of Kansas City (Donna J. Ward, Assistant Vice President) 925 Grand Avenue, Kansas City, Missouri 64198-0001:

1. FirsTier Bancorp, Cheyenne, Wyoming; to become a bank holding by acquiring 100 percent of the voting shares of Union Bank Corporation, and thereby indirectly acquire voting shares of Union State Bank, both of Upton, Wyoming.

Board of Governors of the Federal Reserve System, June 6, 2005.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 05–11528 Filed 6–9–05; 8:45 am]

BILLING CODE 6210–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–05–05CL]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404–371–5983 and send comments to Seleda Perryman, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS–D74, Atlanta, GA 30333 or send an e-mail to *omb@cdc.gov*.

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 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. Written comments should be received within 60 days of this notice.

Proposed Project

Formative Evaluation of Adults' and Children's Views Related to Promotion of Healthy Food Choices—New—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description: In FY 2004, Congress directed the Centers for Disease Control and Prevention (CDC) to conduct formative research on the attitudes of children and parents' regarding nutrition behavior. The FY 04 Appropriation Language instructs CDC to research parents' and children's viewpoints on ''the characteristics of effective marketing of foods to children to promote healthy food choices.'' Upon completion, a report detailing CDC's findings will be submitted to the appropriate Congressional Committees.

In response, CDC has contracted with the Academy for Educational Development (AED) to conduct focus groups to identify key audience concepts around food choices and to develop and test concepts and messages aimed at increasing healthy food choices among children and youth. For the research to be useful to Congress and to the nation's public health agenda, a thorough understanding of a child's attitude toward healthy food choices at varied developmental stages, and the barriers and motivations for adopting and sustaining those choices is essential. Also important is a thorough understanding of those who can influence the health behaviors of children and youth. This research will facilitate the development of messages, strategies, and tactics that resonate with children, youth, parents, and other influencers.

The focus groups will be conducted in three phases: Phase One will address ''tweens'' (ages 9–13) and parents of tweens; Phase 2 will focus on children 6–8 years old and their parents, and Phase 3 will conduct groups with parents of children under 6 years old. The research will begin with tweens. Current market literature and opinion-leaders both strongly suggest that tweens are highly influential in their parents' nutrition decisions, as well as those made by their younger siblings.

For each phase, 36 focus groups will be conducted; thus, three phases will amount to 108 total focus groups. In Phases 1 and 2, focus groups will involve both young people and their parents or key caregivers. In this way, CDC can gain insight into both parents' and children's views, as well as the dynamics of family shared decision-making around food choices and attitudes toward healthy eating patterns. For Phase 3, 36 focus groups about the toddler/young child set (ages 1–5) will be held with their parents and other important influencers such as educators, primary caregivers, and health care providers.

All focus group recruiting will incorporate appropriate representation of diverse ethnic groups, and the groups will be held in several cities to ensure broad geographic representation.

The intent of this audience research is to solicit input and feedback from potential audiences. The information gathered will be used to develop, refine, and modify messages and strategies to increase healthy food choices by children and parents. There is no cost to participants other that their time.

ESTIMATE OF ANNUALIZED BURDEN HOURS

Type of respondents	Number of respondents	Number of responses/ respondents	Average burden/response (in hours)	Total burden (in hrs)
Phase 1: Recruitment	528	1	10/60	88
Phase 1: Tweens (ages 9–13); 24 groups of 11 people per group	264	1	2.0	528
Phase 1: Parents of tweens; 12 groups of 10 people per group	120	1	2.0	240
Phase 2: Recruitment	528	1	10/60	88
Phase 2: Elementary aged children (ages 6–8); 24 groups of 11 children per group)	264	1	2.0	528
Phase 2: Parents of elementary aged children; 12 groups of 10 people per group	120	1	2.0	240
Phase 3: Recruitment	720	1	10/60	120
Phase 3: Parents of preschoolers (ages 1–5); 36 groups of 10 people per group	360	1	2.0	720
Total				2552

Dated: June 6, 2005.

Betsey Dunaway,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. 05–11517 Filed 6–9–05; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[RFA IP05–095]

Effectiveness of a Hospital-Based Program for Vaccination of Birth Mothers and Household Contacts With Inactivated Influenza Vaccine; Notice of Availability of Funds—Amendment

A notice announcing the availability of fiscal year (FY) 2006 funds for a cooperative agreement for Effectiveness of a Hospital-Based Program for Vaccination of Birth Mothers and Household Contacts with Inactivated Influenza Vaccine was published in the **Federal Register**, Thursday, May 12, 2005, Volume 70, Number 91, pages 25079–25084.

The notice is amended as follows: Page 25079, third column, Letter of Intent Deadline, delete June 13, 2005, and replace with August 15, 2005. Page 25079, third column, Application Deadline, delete June 27, 2005, and replace with August 31, 2005. Page 25080, third column, Fiscal Year Funds, delete 2005, and replace with 2006. Page 25080, third column, Anticipated Award Date, delete August 31, 2005, and replace with November 30, 2005. Page 25081, third column, LOI Deadline Date, delete June 13, 2005, and replace with August 15, 2005. Page 25081, third column, Application Deadline Date, delete June 27, 2005, and replace with August 31, 2005. Page 25083, second column, Anticipated Award Date, delete August 31, 2005, and replace with November 30, 2005.

Dated: June 2, 2005.

William P. Nichols,

Director, Procurement and Grants Office, Centers for Disease Control and Prevention.

[FR Doc. 05–11513 Filed 6–9–05; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[RFA IP05–094]

Influenza Vaccination of Children and Accompanying Adults: Mass Vaccination vs Vaccination in Routine Care; Notice of Availability of Funds—Amendment

A notice announcing the availability of fiscal year (FY) 2006 funds for a cooperative agreement for Influenza Vaccination of Children and Accompanying Adults: Mass Vaccination vs Vaccination in Routine Care was published in the **Federal Register,** Thursday, May 12, 2005, Volume 70, Number 91, pages 25067–25071.

The notice is amended as follows: Page 25067, third column, Letter of Intent Deadline, delete June 13, 2005, and replace with August 15, 2005. Page 25067, third column, Application Deadline, delete June 27, 2005, and replace with August 31, 2005. Page 25068, third column, Fiscal Year Funds, delete 2005, and replace with 2006. Page 25068, third column, Anticipated Award Date, delete August 31, 2005, and replace with November 30, 2005. Page 25069, third column, LOI Deadline Date, delete June 13, 2005, and replace with August 15, 2005. Page 25069, third column, Application Deadline Date, delete June 27, 2005, and replace with August 31, 2005. Page 25071, second column, Anticipated Award Date, delete August 31, 2005, and replace with November 30, 2005.

Dated: June 2, 2005.

William P. Nichols,

Director, Procurement and Grants Office, Centers for Disease Control and Prevention.

[FR Doc. 05–11525 Filed 6–9–05; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[RFA IP05–103]

Poliovirus Antibody Seroprevalence Among Inner City Preschool Children, Post-OPV Era; Notice of Availability of Funds—Amendment

A notice announcing the availability of fiscal year (FY) 2005 funds for a cooperative agreement for Poliovirus Antibody Seroprevalence Among Inner City Preschool Children, Post-OPV Era was published in the **Federal Register**, Tuesday, May 10, 2005, Volume 70, Number 89, pages 24594–24598.

This notice has been withdrawn and applications are not being accepted for funding.

Dated: June 2, 2005.

William P. Nichols,

Director, Procurement and Grants Office, Centers for Disease Control and Prevention.

[FR Doc. 05–11526 Filed 6–9–05; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[RFA IP05–088]

Enhancing Utilization of Childhood Immunization Client Recall Practices by Private Providers; Notice of Availability of Funds—Amendment

A notice announcing the availability of fiscal year (FY) 2006 funds for a cooperative agreement for Enhancing Utilization of Childhood Immunization Client Recall Practices by Private Providers was published in the **Federal Register**, Wednesday, May 11, 2005, Volume 70, Number 90, pages 24807–24812.

The notice is amended as follows: Page 24807, first column, Letter of Intent Deadline, delete June 10, 2005, and replace with August 15, 2005. Page 24807, first column, Application Deadline, delete June 27, 2005, and replace with August 31, 2005. Page 24808, second column, Fiscal Year Funds, delete 2005, and replace with 2006. Page 24808, third column, Anticipated Award Date, delete August 31, 2005, and replace with November 30, 2005. Page 24809, second column, LOI Deadline Date, delete June 10, 2005, and replace with August 15, 2005. Page 24809, third column, Application Deadline Date, delete June 27, 2005, and replace with August 31, 2005. Page 24811, third column, Award Date, delete August 31, 2005, and replace with November 30, 2005.

Dated: June 2, 2005.

William P. Nichols,

Director, Procurement and Grants Office, Centers for Disease Control and Prevention.

[FR Doc. 05–11522 Filed 6–9–05; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[RFA IP05–096]

Developing Methods and Strategies to Increase Use of Immunization Registries by Private Providers; Notice of Availability of Funds—Amendment

A notice announcing the availability of fiscal year (FY) 2006 funds for a cooperative agreement for Developing Methods and Strategies to Increase Use of Immunization Registries by Private Providers was published in the **Federal Register**, Wednesday, May 11, 2005, Volume 70, Number 90, pages 24812–24818.

The notice is amended as follows: Page 24812, second column, Letter of Intent Deadline, delete June 10, 2005, and replace with August 15, 2005. Page 24812, second column, Application Deadline, delete June 27, 2005, and replace with August 31, 2005. Page 24814, first column, Fiscal Year Funds, delete 2005, and replace with 2006. Page 24814, first column, Anticipated Award Date, delete August 31, 2005, and replace with November 30, 2005. Page 24815, first column, LOI Deadline Date, delete June 10, 2005, and replace with August 15, 2005. Page 24815, first column, Application Deadline Date, delete June 27, 2005, and replace with August 31, 2005. Page 24817, second column, Award Date, delete August 31, 2005, and replace with November 30, 2005.

Dated: June 2, 2005.

William P. Nichols,

Director, Procurement and Grants Office, Centers for Disease Control and Prevention.

[FR Doc. 05–11523 Filed 6–9–05; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[RFA IP05–091]

Improving Vaccination Coverage in the Greater than 65 Years of Age Population; Notice of Availability of Funds—Amendment

A notice announcing the availability of fiscal year (FY) 2006 funds for a cooperative agreement for Improving Vaccination Coverage in the Greater than 65 Years of Age Population was published in the **Federal Register**,

Thursday, May 12, 2005, Volume 70, Number 91, pages 25075–25079.

The notice is amended as follows: Page 25076, first column, Letter of Intent Deadline, delete June 13, 2005, and replace with August 15, 2005. Page 25076, first column, Application Deadline, delete June 27, 2005, and replace with August 31, 2005. Page 25076, third column, Fiscal Year Funds, delete 2005, and replace with 2006. Page 25076, third column, Anticipated Award Date, delete August 31, 2005, and replace with November 30, 2005. Page 25077, third column, LOI Deadline Date, delete June 13, 2005, and replace with August 15, 2005. Page 25077, third column, Application Deadline Date, delete June 27, 2005, and replace with August 31, 2005. Page 25079, first column, Award Date, delete August 31, 2005, and replace with November 30, 2005.

Dated: June 2, 2005.

William P. Nichols,

Director, Procurement and Grants Office, Centers for Disease Control and Prevention.

[FR Doc. 05–11524 Filed 6–9–05; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Prospective Grant of Exclusive License: Diagnostics of Fungal Infections

AGENCY: Technology Transfer Office, Centers for Disease Control and Prevention (CDC), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: This is a notice in accordance with 35 U.S.C. 209(e) and 37 CFR 404.7(a)(1)(i) that the Centers for Disease Control and Prevention (CDC), Technology Transfer Office, Department of Health and Human Services (DHHS), is contemplating the grant of a worldwide, limited field of use, exclusive license to practice the inventions embodied in the patent application referred to below to AerovectRx (AVRX), Corporation having a place of business in Norcross, Georgia. The patent rights in these inventions have been assigned to the government of the United States of America. The patent applications to be licensed are:

PCT/US02/7973 entitled ''Systems and Methods for Aerosol Delivery of Agents,'' filed 03.13.2002; and,

PCT/US03/019684 entitled ''Mixing Vial,'' filed 06.20.2003.

Status: Pending.

Issue Date: N/A.

The prospective exclusive license will be royalty-bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7.

Technology: This technology adds a new way to deliver vaccines, specifically in mass immunization campaigns.

ADDRESSES: Requests for a copy of this patent application, inquiries, comments, and other materials relating to the contemplated license should be directed to Andrew Watkins, Director, Technology Transfer Office, Centers for Disease Control and Prevention (CDC), 4770 Buford Highway, Mailstop K–79, Atlanta, GA 30341, telephone: (770) 488–8610; facsimile: (770) 488–8615. Applications for a license filed in response to this notice will be treated as objections to the grant of the contemplated license. Only written comments and/or applications for a license which are received by CDC within sixty days of this notice will be considered. Comments and objections submitted in response to this notice will not be made available for public inspection, and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552. A Signed Confidential Disclosure Agreement (available under Forms at *http://www.cdc.gov/tto*) will be required to receive a copy of any pending patent application.

Dated: June 1, 2005.

James D. Seligman

Associate Director for Program Services, Centers for Disease Control and Prevention.

[FR Doc. 05–11512 Filed 6–9–05; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[Program Announce No. ''HHS–2005–ACF–OCS–EI–0053; CFDA 93.602]

Office of Community Services Announcement for Assets for Independence Program Grants

AGENCY: Office of Community Services (OCS), Administration for Children and Families, U.S. Department of Health and Human Services.

ACTION: Notice of availability.

Notice of an amendment to the announcement published on February 9, 2005, concerning the application process for Assets for Independence Program grants. This document announces an additional closing date of July 15, 2005. It also announces two informational telephone conference calls about the Assets for Independence Program and the process for submitting a grant proposal.

The program announcement concerning the application process for Assets for Independence Program grants published on February 9, 2005 in Volume 70, **Federal Register**, pages 6879–6888 is hereby modified. The announcement is modified by adding one additional application due date of July 15, 2005, and a notification of two informational telephone conference calls concerning the Assets for Independence Program and the process for submitting a grant proposal.

SUMMARY: On February 9, 2005, the Office of Community Services, Administration for Children and Families, U.S. Department of Health and Human Services published an announcement seeking applications for the Assets for Independence Program. The announcement appeared in Volume 70, pages 6879–6888 of the **Federal Register**. This document announces one additional application due date of July 15, 2005, which is in addition to the three due dates listed in the February 9 standing announcement (March 15, June 15 and November 1). To be considered timely for this additional due date only, applications must be received at the OCS Operations Center by July 15. (For more details, see submission dates and times section below.)

This document also announces two informational telephone conference calls concerning the Assets for Independence Program and the process for submitting a grant application.

Submission Dates and Times: The new additional closing date for the Assets for Independence Program is July 15, 2005. (This closing date is in addition to three other valid closing dates—March 15, June 15 and November 1—as noted in the current standing announcement.) Applications received after 4:30 p.m. eastern time on the July 15 closing date will be classified as late, and will not be reviewed this cycle.

Deadline: Applications shall be considered as meeting an announced deadline if they are received on or before the due date. Applicants are responsible for ensuring applications are mailed or submitted electronically well in advance of the application due date.

Applications hand carried by applicants, applicant couriers, other representatives of the applicant, or by overnight/express mail couriers shall be

considered as meeting an announced deadline if they are received on or before the deadline date, between the hours of 8 a.m. and 4:30 p.m., eastern time, between Monday and Friday (excluding Federal holidays).

ACF cannot accommodate transmission of applications by facsimile. Therefore, applications transmitted to ACF by fax will not be accepted regardless of date or time of submission and time of receipt.

Receipt acknowledgement for application packages will not be provided to applicants who submit their package via mail, courier services, or by hand delivery. Applicants will receive an electronic acknowledgement for applications that are submitted via Grants.gov.

Late Applications: Applications that do not meet the criteria above are considered late applications. ACF shall notify each late applicant that its application will not be considered in the current competition.

Any application received after 4:30 p.m. eastern time on the deadline date will not be considered for competition.

Applicants using express/overnight mail services should allow two working days prior to the deadline date for receipt of applications. Applicants are cautioned that express/overnight mail services do not always deliver as agreed.

Extension of Deadlines: ACF may extend application deadlines when circumstances such as acts of God (floods, hurricanes, etc.) occur, or when there are widespread disruptions of mail service, or in other rare cases. A determination to extend or waive deadline requirements rests with the Chief Grants Management Officer.

Other Submission Requirements: Submission by Mail: An applicant must provide an original application with all attachments, signed by an authorized representative and two copies. The application must be received at the address below by 4:30 p.m. eastern time on or before the closing date.

Applications should be mailed to: Administration for Children and Families, Office of Community Services' Operations Center, 1515 Wilson Boulevard, Suite 100, Arlington, VA 22209, Attention: Administration for Children and Families, Office of Community Services, Assets for Independence Program.

Hand Delivery: An applicant must provide an original application with all attachments signed by an authorized representative and two copies. The application must be received at the address below by 4:30 p.m. eastern time on or before the closing date. Applications that are hand delivered will be accepted between the hours of 8 a.m. to 4:30 p.m. eastern time, Monday through Friday. Applications should be delivered to: Administration for Children and Families, Office of Community Services' Operations Center, 1515 Wilson Boulevard, Suite 100, Arlington, VA 22209; Attention: Administration for Children and Families, Office of Community Services, Assets for Independence Program.

Electronic Submission: *http://www.Grants.gov*. Please see Section IV.2 Content and Form of Application Submission of the February 9 announcement, for guidelines and requirements when submitting applications electronically.

Informational Conference Calls: The Office of Community Services will host two informational telephone conference calls concerning the Assets for Independence Program and the grant application process on June 20 and 21, 2005 at 2 p.m. until approximately 3 p.m. These calls will be open to all interested individuals. Please call the Office of Community Services on (202) 401–4626 or go to the OCS Asset Building Web site at *http://www.acf.hhs.gov* to register for a call and for dial-in information. Participants are strongly encouraged to register, as the number of lines is limited. OCS plans to make handout materials available to all individuals who register for either of the informational calls.

Announcement Availability: The Assets for Independence Program announcement and all application materials are available at *http://www.Grants.gov*. Standard forms and certifications may also be found at *http://www.acf.hhs.gov/programs/ofs/forms.htm*. Finally, the OCS Asset Building Web site at *http://www.acf.hhs.gov/assetbuilding* provides much information about the Assets for Independence Program and the application process. The page includes links to all required forms as well as to a guidebook for developing an AFI Project and applying for an AFI grant.

FOR FURTHER INFORMATION CONTACT: James Gatz, Manager, Assets for Independence Program, Telephone: (202) 401–4626 or e-mail: *AFIProgram@acf.hhs.gov*. An array of helpful information is posted on the OCS Asset Building Web site at *http://www.acf.hhs.gov/assetbuilding*.

Dated: June 6, 2005.

Josephine B. Robinson,

Director, Office of Community Services.

[FR Doc. 05–11584 Filed 6–9–05; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

ACYF/FYSB; Notice of Clarification for the FY 05 Community-Based Abstinence Education Program Announcement HHS–2005–ACF–ACYF–CE–0099, CFDA# 93.010

AGENCY: Family and Youth Services Bureau (FYSB), Administration on Children, Youth, and Families (ACYF), ACF, HHS.

ACTION: Notice of clarification.

SUMMARY: This notice is to inform interested parties of a clarification to the Community-Based Abstinence Education Announcement that was published on May 20, 2005. The following clarification must be noted:

FYSB recognizes that abstinence education, as it has been so successfully implemented across the country, achieves a very beneficial impact on the development of youth in every aspect. Applicants should note that Community-Based Abstinence Education applications will only be evaluated on the extent to which they satisfy the specific eligibility criteria outlined in Section *III. Eligibility* and the evaluation criteria outlined in Section *V.I Evaluation Criteria,* which include an agency's experience and commitment to Abstinence Education as defined by Section 510(b)(2) of Title V of the Social Security Act. Curricula developed or selected for implementation in the Community-Based Abstinence Education grant program must be responsive to the eight elements of the Section 510 abstinence education definition (elements A through H) and may not be inconsistent with any aspect of this definition.

For the purposes of this announcement, a Positive Youth Development approach shall mean programs that help young people to abstain from sexual activity until marriage.

For further information about this clarification or any aspects thereof related to the Community-Based Abstinence Education program please contact Jeffrey Trimbath, Director, Abstinence Education, Family and Youth Services Bureau at 1–866–796–1591.

Dated: June 7, 2005.

Wade F. Horn,

Assistant Secretary for Children and Families.

[FR Doc. 05–11582 Filed 6–9–05; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0386]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Guidance for Industry on Formal Dispute Resolution: Scientific and Technical Issues Related to Pharmaceutical Current Good Manufacturing Practice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Guidance for Industry on Formal Dispute Resolution: Scientific and Technical Issues Related to Pharmaceutical Current Good Manufacturing Practice'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Karen Nelson, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of March 15, 2005 (70 FR 12697), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency 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. OMB has now approved the information collection and has assigned OMB control number 0910–0563. The approval expires on May 31, 2008. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets*.

Dated: June 6, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–11501 Filed 6–9–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0401]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Customer/Partner Services Surveys

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Customer/Partner Services Surveys'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: JonnaLynn P. Capezzuto, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of March 4, 2005, (70 FR 10648), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency 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. OMB has now approved the information collection and has assigned OMB control number 0910–0360. The approval expires on May 31, 2008. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets*.

Dated: June 6, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–11502 Filed 6–9–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0210]

Agency Information Collection Activities; Proposed Collection; Comment Request; Veterinary Feed Directive

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including renewal of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on reporting and recordkeeping requirements for distribution and use of Veterinary Feed Directive (VFD) drugs and animal feeds containing VFD drugs.

DATES: Submit written or electronic comments on the collection of information by August 9, 2005.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.fda.gov/dockets/ecomments*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, rm. 4B–41, Rockville, MD 20857, 301–827–1472.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of a proposed collection of information as set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether

the information will have practical utility; (2) the accuracy of FDA s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Veterinary Feed Directive (OMB Control Number 0910–0363)—Extension

With the passage of Animal Drug Availability Act (ADAA), the Congress enacted legislation establishing a new class of restricted feed use drugs, VFD drugs, which may be distributed without involving State pharmacy laws. Although controls on the distribution and use of VFD drugs are similar to those for prescription drugs regulated under section 503(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(f)), the implementing VFD regulation (21 CFR 558.6), is tailored to the unique circumstances relating to the distribution of medicated feeds. The content of the VFD is spelled out in the regulation. All distributors of medicated feed containing VFD drugs must notify FDA of their intent to distribute, and records must be maintained of the distribution of all medicated feed containing VFD drugs. The VFD regulation ensures the protection of public health while enabling animal producers to obtain and use needed drugs as efficiently and cost-effectively as possible.

FDA estimates the burden for this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
558.6(a)(3) through (a)(5)	15,000	25	375,000	0.25	93,750
558.6(d)(1)(i) through (d)(1)(iii)	500	1	500	0.25	125
558.6(d)(1)(iv)	20	1	20	0.25	5
558.6(d)(2)	1,000	5	5,000	0.25	1,250
514.1(b)(9)	1	1	1	3.00	3
Total Hours	16,521				95,133

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeper	Total Annual Records	Hours per Record	Total Hours
558.6(c)(1) through (c)(4)	112,500	10	1,125,000	.0167	18,788
558.6(e)(1) through (e)(4)	5,000	75	375,000	.0167	6,263
Total Hours					25,051

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The estimate of the times required for record preparation and maintenance is based on agency communication with industry and agency records and experience.

Dated: June 6, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–11581 Filed 6–9–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, DHHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: (301) 496–7057; fax: (301) 402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Identification of H2–Db and HLA–A2 Specific CD8 Epitopes From Human KDR/VEGFR–2 That Inhibit Angiogenesis by Vaccination

Drs. Samir Khleif and Yujun Dong (NCI).

U.S. Provisional Application No. 60/671,867 filed 15 Apr 2005 (DHHS Reference No. E–158–2005/0–US–01).

Licensing Contact: John Stansberry; (301) 435–5236; *stansbej@mail.nih.gov.*

Vascular Endothelial Growth Factor Receptor 2 (VEGFR–2/KDR) is a promising target for cancer therapy due to its critical role in tumor associated angiogenesis and vascularization. This invention describes the amino acid sequences of seven short peptides based upon epitopes of human Vascular Endothelial Growth Factor Receptor-2

(VEGFR–2) that bind human Histocompatibility Leukocyte Antigen A2 (HLA-A2). These peptides can potentially induce Cytotoxic T Lymphocyte (CTL)-mediated lysis of tumor vascularization and inhibit tumor growth. The inventors have demonstrated the principles described in this invention in vivo in mice for VEGFR–2, using murine H2-Db specific peptides instead of HLA-A2. This invention has the potential to inhibit angiogenesis and may be applicable to tumor and autoimmune disease therapy.

In addition to licensing, the technology is available for further development through collaborative research opportunities with the inventors.

Novel Anti-CD30 Antibodies and Recombinant Immunotoxins Containing Disulfide-Stabilized Fv Fragments

Ira H. Pastan *et al.* (NCI).
U.S. Provisional Application No. 60/387,293 filed 07 Jun 2002 (DHHS Reference No. E–135–2002/0–US–01);
PCT Application No. PCT/US03/18373 filed 07 Jun 2003, which published as WO 03/104432 on 18 Dec 2003 (DHHS Reference No. E–135–2002/1–PCT–01);
U.S. Patent Application filed 03 Dec 2004 (DHHS Reference No. E–135–2002/1–US–02).
Licensing Contact: Jesse S. Kindra; (301) 435–5559; *kindraj@mail.nih.gov.*

The present invention discloses the creation of new anti-CD30 stalk antibodies and anti-CD30 dsFv-immunotoxins, which have shown good cytotoxic activity.

CD30 is a member of the tumor necrosis factor receptor super family. It is an excellent target due to its high expression in malignant Reed Sternberg cells of Hodgkin's Lymphoma (HL) and in anaplastic large cell lymphomas (ALCL), and due to its expression in only a small subset of normal lymphocytes. Previous attempts to target CD30 include the scFv immunotoxin Ki-4 that has shown specific binding to CD30-positive lymphoma cell lines and killed target cells.

As claimed in this patent application, some of the antibodies do not bind or bind very weakly CD30 released from cells, although they do bind strongly to cell associated CD30. This enhancement further increases the ability of immunotoxins and other immunoconjugates to target and treat lymphomas expressing CD30.

The immunotoxins of the present invention are more stable and have higher affinity for CD30 then their predecessors. Research thus far has shown that the dsFv-immunotoxins are able to kill a variety of CD30-positive lymphoma cell lines in vitro as well as CD30-transfected A431 cells via specific binding to CD30.

In addition to licensing, the technology is available for further development through collaborative research opportunities with the inventors.

Compositions and Methods for Inhibiting Vascular Channels and Methods of Inhibiting Proliferation

Myung Hee Park, Paul M.J. Clement, Hartmut M. Hanauske-Abel, Edith C. Wolff, Hynda K. Kleinman, Bernadette M. Cracchiolo (NIDCR).
U.S. Provisional Application No. 60/314,561 filed 23 Aug 2001 (DHHS Reference No. E–320–2001/0–US–01);
PCT Application No. PCT/US02/26909 filed 23 Aug 2002, which published as WO 03/018014A2 on 06 Mar 2003 (DHHS Reference No. E–320–2001/0–PCT–02);
U.S. Patent Application No. 10/486,671 filed 11 May 2004 (DHHS Reference No. E–320–2001/0–US–03).
Licensing Contact: John Stansberry; (301) 435–5236; *stansbej@mail.nih.gov.*

Angiogenesis, the recruitment of new blood vessels, is recognized as an important factor in tumor proliferation in many types of cancer. It is generally accepted that therapeutic approaches that inhibit angiogenesis effectively limit, or even prevent, the formation of solid tumors. It has also been shown that anti-angiogenic therapeutics allow conventional radiation therapy and chemotherapy to be more effective.

This invention pertains to certain compounds that inhibit angiogenesis in a previously unrecognized way. These compounds also inhibit the proliferation of cells within intraepithelial neoplasias (clusters of abnormally proliferating epithelial cells that are the origin of cancers). The subject compounds specifically block the formation of the amino acids hypusine and hydroxyproline. The former is the critical residue of eukaryotic translation initiation factor 5A (eIF5A), which is important in cell cycle progression, and hydroxyproline constitutes the critical residue of the collagens. The targeted enzymes are deoxyhypusine hydroxylase and prolyl 4-hydroxylase, respectively.

This invention provides evidence for an important role of eIF–5A in angiogenesis, and discloses a family of compounds with useful clinical properties. Specifically, these compounds include the core structures and potential derivatives of ciclopirox olamine, deferiprone, deferoxamine, and 2,2'-dipyridyl.

Ciclopirox olamine has potential for treatment of oral-pharyngeal cancer, and chemoprevention and treatment of cervical and vulvar cancer. Notably, this drug is FDA-approved in the USA as a topical medication against fungal infections while, in Europe, it is also approved for the treatment of yeast infections of the genital tract. The compound has a known clinical profile and lacks teratogenicity, potentially expediting clinical trials for new cancer treatment indications.

Dated: June 3, 2005.

Steven M. Ferguson,

Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 05–11575 Filed 6–9–05; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing: 3-Hydroxy-3-Methylglutaryl Coenzyme A Reductase Inhibitors as a Modality in Cancer Therapy

AGENCY: National Institutes of Health, Public Health Service, DHHS.

ACTION: Notice.

SUMMARY: The invention described below is owned by an agency of the U.S. Government and is available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: Licensing information may be obtained by contacting George G. Pipia, Ph.D., at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: (301) 435–5560; fax: (301) 402–0220; e-mail: *PipiaG@mail.nih.gov*.

Use of Inhibitors of 3-Hydroxy-3-Methylglutaryl Coenzyme A Reductase as a Modality in Cancer Therapy

Charles Myers, Jane Trepel, Won Ki Kang, Luke Whitsell, Leonard Neckers (NCI). U.S. Patent No. 6,040,334 issued 21 Mar 2000 (DHHS Reference No. E–146–1992/0–US–23).

Licensing Contact: George Pipia; 301/435–5560; *pipiag@mail.nih.gov*.

The invention provides a method for treating mammalian adenocarcinomas and sarcomas comprising administration of an effective amount of an inhibitor of HMG Co-A or homologues of the inhibitor. Adenocarcinoma is known to afflict the prostate, stomach, lung, breast and colon, as well as other sites. Examples of compounds useful in the present invention are lovastatin and simvastatin as well as their homologues. Also included are compounds classified as HMG Co-A inhibitors, as well as their homologues or analogues. Generally, these HMG Co-A inhibitors are known to lower serum cholesterol in humans. However, the present invention is not so limited. That is, an inhibitor of HMG Co-A or one of its homologues may work in the method of the present invention without necessarily lowering serum cholesterol. The invention focuses not on the compound's ability to lower cholesterol, but rather on the compound's ability to treat selected cancers, such as adenocarcinomas of the prostate, stomach, lung, breast and colon and certain sarcomas such as Ewing's sarcoma.

Also provided by the invention is a method of reducing prostate specific antigen (PSA) levels in a patient having prostatic adenocarcinoma comprising administration of an effective amount of a compound which is an inhibitor of HMG Co-A or a homologue of such inhibitor. The invention also includes a method of reducing PSA in conjunction with another treatment modality.

The claims encompassing this technology are directed to the methods of treating certain types of cancer with inhibitors of HMG Co-A reductase, and specifically with lovastatin and simvastatin (see the U.S. issued patent 6,040,334: *http://patft.uspto.gov/netacgi/nph-Parser?Sect1=PTO1&Sect2=HITOFF&d=PALL&p=1&u=/netahtml/srchnum.htm&r=1&f=G&l=50&s1=6,040,334.WKU.&OS=PN/6,040,334&RS=PN/6,040,334)*.

In addition to licensing, the technology is available for further development through collaborative research opportunities with the inventors.

Dated: June 3, 2005.

Steven M. Ferguson,

Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 05–11576 Filed 6–9–05; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, DHHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: (301) 496–7057; fax: (301) 402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Proteomic Profiles Associated With Aging

Dr. Shari M. Ling (NIA).
DHHS Reference No. E–354–2004/1—Research Tool.
Licensing Contact: Marlene Shinn-Astor; 301/435–4426; *shinnm@mail.nih.gov*.

This invention relates to proteomic profiles associated with normal aging. Biological markers (Biomarkers) that characterize the state of ''normal aging'' could provide a useful comparison for biomarkers of age-associated diseases (cardiovascular, cancer, arthritis). The profiles could then be used to develop markers linked with other diseases.

The proteins identified could either be included in elisa or multiplex assays, or incorporated into a protein-based chip. These products would be of utility to characterize research subjects for clinical trials. Specific proteins or groups of proteins could be used as potential therapeutic targets to prevent or attenuate disease development or help to improve the normal aging process.

In addition to licensing, the technology is available for further development through collaborative research opportunities with the inventors.

AlphaB-Crystallin/HSPBE Gene Knockout Mouse

Dr. Eric F. Wawrousek, et al. (NEI).
DHHS Reference No. E–135–2001/0—Research Tool.
Licensing Contact: Marlene Shinn-Astor; (301) 435–4426; *shinnm@mail.nih.gov*.

The alpha crystallins and other members of the small heat shock family of proteins, have been shown to be very important proteins for preventing the irreversible destruction of other proteins. AlphaA is mostly restricted to the ocular lens, while alphaB is present in almost all cells of the body with the highest levels in ocular lens, heart, and skeletal muscle. The NIH has created lines of mice, which lack the alphaB-crystallin gene (and unintentionally, its neighboring gene HSPB2). These mouse lines could be used to study functions of these proteins in the eye, skeletal muscle, heart, and any other tissue or organ.

In addition to licensing, the technology is available for further development through collaborative research opportunities with the inventors.

Three Myelin Basic Protein-Specific T Cell Clones, TL2A6, TL5F6, and TL5G7 That Are Restricted by Multiple Sclerosis-Associated HLA–DR Molecules and Recognize the Immunodominant Myelin Basic Protein (MBP) Peptide MBP (83–99)

Dr. Roland Martin, *et al.* (NINDS).
DHHS Reference No. E–277–1999/0—Research Tool.
Licensing Contact: Marlene Shinn-Astor; (301) 435–4426; *shinnm@mail.nih.gov.*

Autoreactive T cell clones such as TL3A6 and TL5F6 that recognize an autoantigen, which is potentially relevant for an autoimmune disease, for example, multiple sclerosis (MS), offer the potential to examine the disease pathogenesis and develop new treatments. Such treatments aim at disrupting or interfering with the specific interaction between autoreactive T cells, antigen presenting cells and antigenic peptide. Current treatments have immunomodulatory effects and side effects. These T cell lines will be useful for developing novel treatment approaches for multiple sclerosis. The T cell lines can be used to test treatments that block or interfere with surface receptors of these cells.

Mouse Model for Myasthenia Gravis

Dr. Michael J. Lenardo et al. (NIAID).
DHHS Reference No. E–188–1999/0—Research Tool.

Licensing Contact: Marlene Shinn-Astor; (301) 435–4426; *shinnm@mail.nih.gov.*

Myasthenia gravis is a disease that causes muscle weakness and paralysis due to an autoimmune process that attacks the muscle. So far no mouse model has been available which has limited investigation of the disease and the development of better treatments or a cure. Our inventors have created a transgenic mouse strain that manifests immunological reactivity that underlines myasthenia gravis.

Use of Transgenic Mice To Assess the Systemic Effects of Tissue Inhibitor of Metalloproteinases-1 (TIMP) on Tumor Progression, Liver Fibrosis, Rheumatoid Arthritis, Wound Healing, and Angiogenesis

Dr. Unnur P. Thorgeirsson, et al. (NCI). DHHS Reference No. E–273–1998/0—Research Tool.

Licensing Contact: Marlene Shinn-Astor; (301) 435–4426; *shinnm@mail.nih.gov.*

NIH researchers have produced transgenic mice over expressing human tissue inhibitor of metalloproteinases-1 (hTIMP) in the liver under the control of an albumin promoter. These mice produce large amounts of hTIMP–1 for extended periods of time, resulting in high levels of biologically active inhibitor released into the systemic circulation. In considering that the sustained high levels of circulating hTIMP–1 do not appear to affect the general health of these mice, this model can be used to study the protective effects of TIMP–1 on diseases, which involve extensive proteolytic matrix degradation and tissue remodeling. Examples of such diseases include malignant tumors, liver fibrosis, wound healing, rheumatoid arthritis, and a variety of angioproliferative diseases.

Dated: June 3, 2005.

Steven M. Ferguson,

Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 05–11577 Filed 6–9–05; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the Board of Scientific Counselors, National Cancer Institute.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the National Cancer Institute, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors, National Cancer Institute, Subcommittee 1—Clinical Sciences and Epidemiology.

Date: July 11–12, 2005

Time: July 11, 2005, 7 p.m. to 11 p.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: Holiday Inn Select Bethesda, Versailles I, 8120 Wisconsin Avenue, Bethesda, MD 20814.

Time: July 12, 2005, 9 a.m. 3:30 p.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: National Institutes of Health, National Cancer Institute, 9000 Rockville Pike, Building 31, Conference Room 10, Bethesda, MD 20892.

Contact Person: Brian E. Wojcik, PhD, Senior Review Administrator, Institute Review Office, Office of the Director, National Cancer Institute, 6116 Executive Boulevard, Room 2114, Bethesda, MD 20892, (301) 496–7628, *wojcikb@mail.nih.gov*.

In the interest of security, NIH has instituted stringent procedures for entrance into the building by non-government employees. Persons without a government I.D. will need to show a photo I.D. and sign-in at the security desk upon entering the building.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS.)

Dated: June 6, 2005

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05–11571 Filed 6–9–05; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. appendix 2), notice is hereby given of a meeting of the Board of Scientific Counselors, National Cancer Institute. The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the National Cancer Institute, including consideration of personnel qualifications and performance, and the competence of individual investgators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors, National Cancer Institute, Subcommittee 2—Basic Sciences.

Date: July 11, 2005.

Time: 10 a.m. to 3:30 p.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: National Institutes of Health, National Cancer Institute, 9000 Rockville Pike, Building 31, Conference Room 6, Bethesda, MD 20892.

Time: 7 p.m. to 11 p.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: Holiday Inn Select Bethesda, Versailles I, 8120 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Florence E. Farber, PhD, Health Scientific Administrator, Office of the Director, National Cancer Institute, National Institutes of Health, 6116 Executive Boulevard, Room 2115, Bethesda, MD 20892, (301) 496–7628, *ff6p@nih.gov*.

In the interest of security, NIH has instituted stringent procedures for entrance into the building by non-government employees. Persons without a government I.D. will need to show a photo I.D. and sign-in at the security desk upon entering the building.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS.)

Dated: June 6, 2005.

LaVerne Y. Stringfield,

Direcotr, Office of Federal Advisory Committee Policy.

[FR Doc. 05–11572 Filed 6–9–05:8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Microbiology, Infectious Diseases and AIDS Initial Review Group, Microbiology and Infectious Diseases Research Committee, Microbiology & Infectious Diseases Research Committee (MIDRC) June 2005.

Date: June 23–24, 2005.

Time: 8 a.m. to 1 p.m.

Agenda: To review and evaluate grant applications.

Place: Marriott Washington, 1221 22nd Street, NW., Washington, DC 20037.

Contact Person: Annie Walker-Abbey, PhD, Scientific Review Administrator, Scientific Review Program, Division of Extramural Activities, National Institutes of Health/NIAID, 6700B Rockledge Drive, RM. 3266, Bethesda, MD 20892–7616, (301) 451–2671, *aabbey@niaid.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS.)

Dated: June 1, 2005.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05–11559 Filed 6–9–05; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institutes of General Medical Sciences; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of General Medical Sciences Special Emphasis Panel, Predictive ADME–Tox.

Date: June 30–July 1, 2005.

Time: 9 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn Select Bethesda, 8120 Wisconsin Ave, Bethesda, MD 20814.

Contract Person: Laur K. Moen, PhD, Scientific Review Administrator, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, Natcher Building, Room 3AN–12, Bethesda, MD 20892, 301–594–3998, *moenl@nigms.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives, National Institutes of Health, HHS).

Dated: June 1, 2005.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05–11560 Filed 6–9–05; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of General Medical Sciences Special Emphasis Panel, Postdoctoral Research Training in the Biomedical Sciences.

Date: June 29, 2005.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda Marriott Suites, 6711 Democracy Boulevard, Bethesda, MD 20817.

Contact Person: Brian R. Pike, PhD., Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, Room 3AN18, Bethesda, MD 20892, 301–594–3907, *pikbr@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Development Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives, National Institutes of Health, HHS)

Dated: June 1, 2005.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05–11561 Filed 6–9–05; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Child Health and Human Development; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set in forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material,

and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Child Health and Human Development Initial Review Group, Biobehavioral and Behavioral Sciences Subcommittee.

Date: June 29–30, 2005.

Time: 9 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda Park Hotel, 8400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Cedil C. Booker, BS, Grants Technical Assistant, National Institutes of Health, National Institute of Child Health and Human Development, 6100 Executive Blvd Room 5B01, Bethesda, MD 20814, (301) 435–6901, *bookerce@od.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: June 1, 2005.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05–11562 Filed 6–9–05; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Child Health and Human Development; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Child Health and Human Development Special Emphasis Panel, Molecular Basis of Male Infertility.

Date: June 29, 2005.

Time: 9 a.m. to 1 p.m.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn Select, 8120 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Jon M. Ranhand, PhD, Scientist Review Administrator, Division of Scientific Review, National Institute of Child Health and Human Development, NIH, 6100 Executive Boulevard, Room 5B01, Bethesda, MD 20892, (301) 435–6884, *ranhandj@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment, Program, National Institutes of Health, HHS)

Dated: June 1, 2005.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05–11563 Filed 6–9–05; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Child Health and Human Development; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Child Health and Human Development Special Emphasis Panel, Hepatocyte Growth Factor and Ovarian Granulosa Cell Apoptosis.

Date: June 24, 2005.

Time: 11 a.m. to 1 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Child Health and Human Devel, 6100 Executive Blvd. 5B01, Rockville, MD 20892, (Telephone Conference Call).

Contact Person: Jon M. Ranhand, PhD, Scientist Review Administrator, Division of Scientific Review, National Institute of Child Health, and Human Development, NIH, 6100 Executive Boulevard, Room 5B01, Bethesda, MD 20892, (301) 435–6884, *ranhandj@mail.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: Jane 1, 2005.

LaVern Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05–11564 Filed 6–9–05; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Child Health and Human Development; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552(c)(6), Title U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal property.

Name of Committee: National Institute of Child Health and Human Development Initial Review Group Reproduction, Andrology, and Gynecology Subcommittee.

Date: June 27–28, 2005.

Time: 1 p.m. to 2 p.m.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn Select, 8120 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Jon M. Ranhand, PhD, Scientist Review Administrator, Division of Scientific Review, National Institute of Child Health and Human Development, NIH, 6100 Executive Boulevard, Room 5B01, Bethesda, MD 20892, (301) 435–6884, *ranhandj@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: June 1, 2005.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05–11565 Filed 6–9–05; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Biomedical Imaging and Bioengineering; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Biomedical Imaging and Bioengineering Special Emphasis Panel, R13 Grants Review.

Date: June 23, 2005.

Time: 1:30 p.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard 223, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Prabha L. Atreya, PhD, Scientific Review Administrator, Office of Scientific Review, National Institute of Biomedical Imaging and Bioengineering, Bethesda, MD 20892, (301) 496–8633, *atreyapr@mail.nih.gov.*

Dated: June 3, 2005.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05–11569 Filed 6–9–05; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5. U.S.C. appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Environmental Health Sciences Special Emphasis Panel, NTP Statistical Analyses.

Date: June 21, 2005.

Time: 10:30 a.m. to 5 p.m.

Agenda: To review and evaluate contract proposals.

Place: NIEHS/National Institutes of Health, Building 4401, East Campus, 79 T.W. Alexander Drive, Research Triangle Park, NC 27709 (Telephone Conference Call).

Contact Person: RoseAnne M. McGee, Associate Scientific Review Administrator, Scientific Review Branch, Office of Program Operations, Division of Extramural Research and Training, Nt. Inst. of Environmental Health Sciences, P.O. Box 12233, MD EC–30, Research Triangle Park, NC 27709, 919/541–0752.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.115, Biometry and Risk Estimation—Health Risks from Environmental Exposures; 93.142, NIEHS Hazardous Waste Worker Health and Safety Training; 93.143, NIEHS Superfund Hazardous Substances—Basic Research and Education; 93.894, Resources and Manpower Development in the Environmental Health Sciences; 93.113, Biological Response to Environmental Health Hazards; 93.114, Applied Toxicological Research and Testing, National Institutes of Health, HHS).

Dated: June 3, 2005.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05–11570 Filed 6–9–05; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel, ''Biodefense and Emerging Infectious Disease Research Opportunities''.

Date: June 23, 2005.

Time: 11 a.m. to 2:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6700–B Rockledge Drive, Rm #3137, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Hagit S David, PhD, Scientific Review Administrator, Scientific Review Program, Division of Extramural Activities, National Institutes of Health/NIAID, 6700–B Rockledge Drive, MSC 7616, Bethesda, MD 20892–7616, (301) 402–4596, *hdavid@niaid.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS.)

Dated: June 6, 2005.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05–11573 Filed 6–9–05; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material,

and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Mental Health Special Emphasis Panel, Depression.

Date: June 23, 2005.

Time: 11 a.m. to 12:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: A. Roger Little, PhD, Scientific Review Administrator, Division of Extramural Activities, National Institute of Mental Health, National Institutes of Health, 6001 Executive Blvd., Room 6157, MSC 9609, Rockville, MD 20852–9609, (301) 402–5844, *alittle@mail.nih.gov*.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: National Institute of Mental Health Special Emphasis Panel, NRSA Individual Fellowships.

Date: July 12, 2005.

Time: 10 a.m. to 2:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Aileen Schulte, PhD, Scientific Review Administrator, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd, Room 6140, MSC 9608, Bethesda, MD 20892–9608, (301) 443–1225, *aschulte@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.242, Mental Health Research Grants; 93.281, Scientist Development Award, Scientist Development Award for Clinicians, and Research Scientist Award; 93.282, Mental Health National Research Service Awards for Research Training, National Institutes of Health, HHS.)

Dated: June 6, 2005.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05–11574 Filed 6–9–05; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Diet, Obesity, and Genes: DIOGenes.

Date: July 7, 2005.

Time: 1 p.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: D.G. Patel, PhD., Scientific Review Administrator, Review Branch, DEA, NIDDK, National Institutes of Health, Room 755, 6707 Democracy Boulevard, Bethesda, MD 20892–5452 (301) 594–7682; *pateldg@niddk.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS.)

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05–11580 Filed 6–9–05; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. appendix 2), notice is hereby given of the following meetings.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel, ZRG1 DIG F (50) Bioengineering.

Date: June 10, 2005.

Time: 11 a.m. to 1 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call.)

Contact Person: Rass M. Shayiq, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2182, MSC 7818, Bethesda, MD 20892, (301) 435–2359, *shayiqr@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Cardiovascular Dynamics.

Date: June 29, 2005.

Time: 1 p.m. to 2 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call.)

Contact Person: Ai-Ping, Zou, PhD, MD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4118, MSC 7814, Bethesda, MD 20892, 301–435–1777, *zouai@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, Yellow Fever Mosquito.

Date: June 29, 2005.

Time: 3 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Fouad A. El-Zaatari, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3206, MSC 7808, Bethesda, MD 20892, (301) 435–1149, *elzaataf@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS.)

Dated: June 1, 2005.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05–11566 Filed 6–9–05; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Center for Scientific Review Special Emphasis Panel, June 30, 2005, 8:30 a.m. to June 30, 2005, 3 p.m., Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814 which was published in the **Federal Register** on May 31, 2005, 70 FR 30958–30961.

The meeting title has been changed to ''Small Business: Digestive Sciences''. The meeting is closed to the public.

Dated: June 1, 2005.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05–11567 Filed 6–9–05; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Center for Scientific Review Special Emphasis Panel, June 30, 2005, 8 a.m. to June 30, 2005, 5 p.m., Hyatt Regency Bethesda, One Bethesda Metro Center, Bethesda, MD, 20814 which was published in the **Federal Register** on May 31, 2005, 70 FR 30956–30961.

The meeting title has been changed to ''Small Business: Pulmonary Sciences''. The meeting is closed to the public.

Dated: June 1, 2005.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05–11568 Filed 6–9–05; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[USCG–2005–21232]

Beacon Port Natural Gas Deepwater Port License Application; Preparation of Environmental Impact Statement

AGENCY: Coast Guard, DHS; Maritime Administration, DOT.

ACTION: Notice of intent; notice of public meetings; request for comments.

SUMMARY: The Coast Guard and the Maritime Administration (MARAD) announce that the Coast Guard intends to prepare an environmental impact statement (EIS) as part of the environmental review of this license application. The application describes a project that would be located in the Gulf of Mexico, in lease block High Island Area 27, on the outer Continental Shelf (OCS). The Main Terminal would be located approximately 45 miles South of High Island and 50 miles East-Southeast of Galveston, Texas, with a riser platform in lease block West Cameron 167, approximately 27 miles South of Holly Beach and 29 miles South-Southeast of Johnson?s Bayou, Louisiana. Publication of this notice begins a scoping process that will help identify and determine the scope of environmental issues to be addressed in the EIS. This notice requests public participation in the scoping process and provides information on how to participate.

DATES: The public meeting in Corpus Christi, Texas will be held on June 28, 2005; the public meeting in Galveston, Texas will be held on June 29, 2005; and the public meeting in Lafayette, Louisiana will be held on June 30, 2005. Each public meeting will be held from 5 p.m. to 7 p.m. and will be preceded by an open house from 3 p.m. to 4:30 p.m. Public meetings may end earlier or later than the stated time, depending on the number of persons wishing to speak. Material submitted in response to the request for comments must reach the Docket Management Facility by July 11, 2005.

ADDRESSES: The public meetings will be held at:

Omni Bayfront Tower, 900 North Shoreline Boulevard, Corpus Christi, TX 78401; telephone 361–887–1600;

San Luis Resort, 5222 Seawall Blvd, Galveston, TX 77551; telephone 409–744–1500; and

Holiday Inn Central, 2032 NE Evangeline Thruway, Lafayette, LA 70501; telephone 337–233–6815.

Address docket submissions for USCG–2005–21232 to: Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street SW., Washington, DC 20590–0001.

The Docket Management Facility accepts hand-delivered submissions, and makes docket contents available for public inspection and copying at this address, in room PL–401, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Facility's telephone is 202–366–9329, its fax is 202–493–2251, and its website for electronic submissions or for electronic access to docket contents is *http://dms.dot.gov.*

FOR FURTHER INFORMATION CONTACT: Ray Martin, U.S. Coast Guard, telephone: 202–267–1683, e-mail: *rmartin@comdt.uscg.mil.* If you have questions on viewing the docket, call Andrea M. Jenkins, Program Manager, Docket Operations, telephone: 202–366–0271.

SUPPLEMENTARY INFORMATION:

Public Meetings and Open Houses

We invite you to learn about the proposed deepwater port at an informational open house, and to comment at a public meeting on environmental issues related to the proposed deepwater port. Your comments will help us identify and refine the scope of the environmental issues to be addressed in the EIS.

In order to allow everyone a chance to speak at the public meetings, we may limit speaker time, or extend the meeting hours, or both. You must identify yourself, and any organization you represent, by name. Your remarks will be recorded or transcribed for inclusion in the public docket.

You may submit written material at a public meeting, either in place of or in addition to speaking. Written material must include your name and address, and will be included in the public docket.

Public docket materials will be made available to the public on the Docket Management Facility's Docket Management System (DMS). See ''Request for Comments'' for information about DMS and your rights under the Privacy Act.

All our public meeting locations are wheelchair-accessible. If you plan to attend an open house or public meeting, and need special assistance such as sign

language interpretation or other reasonable accommodation, please notify the Coast Guard (see **FOR FURTHER INFORMATION CONTACT**) at least 3 business days in advance. Include your contact information as well as information about your specific needs.

Request for Comments

We request public comments or other relevant information on environmental issues related to the proposed deepwater port. The public meetings are not the only opportunity you have to comment. In addition to or in place of attending a meeting, you can submit comments to the Docket Management Facility during the public comment period (see **DATES**). We will consider all comments and material received during the comment period.

Submissions should include:

- Docket number USCG–2005–21232.
- Your name and address.
- Your reasons for making each comment or for bringing information to our attention.

Submit comments or material using only one of the following methods:

- Electronic submission to DMS, *http://dms.dot.gov.*
- Fax, mail, or hand delivery to the Docket Management Facility (see **ADDRESSES**). Faxed or hand delivered submissions must be unbound, no larger than 8½ by 11 inches, and suitable for copying and electronic scanning. If you mail your submission and want to know when it reaches the Facility, include a stamped, self-addressed postcard or envelope.

Regardless of the method used for submitting comments or material, all submissions will be posted, without change, to the DMS Web site (*http://dms.dot.gov*), and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to read the Privacy Act notice that is available on the DMS Web site, or the Department of Transportation Privacy Act Statement that appeared in the **Federal Register** on April 11, 2000 (65 FR 19477).

You may view docket submissions at the Docket Management Facility (see **ADDRESSES**), or electronically on the DMS website.

Background

Information about deepwater ports, the statutes, and regulations governing their licensing, and the receipt of the current application for a liquefied natural gas (LNG) deepwater port appears at 70 FR 29776, May 24, 2005. The ''Summary of the Application'' from that publication is reprinted below for your convenience.

Consideration of a deepwater port license application includes review of the proposed deepwater port's natural and human environmental impacts. The Coast Guard is the lead agency for determining the scope of this review, and in this case the Coast Guard has determined that review must include preparation of an EIS. This notice of intent is required by 40 CFR 1508.22, and briefly describes the proposed action and possible alternatives and our proposed scoping process. You can address any questions about the proposed action, the scoping process, or the EIS to the Coast Guard official identified in **FOR FURTHER INFORMATION CONTACT**.

Proposed Action and Alternatives

The proposed action requiring environmental review is the Federal licensing of the proposed deepwater port described in ''Summary of the Application'' below. The alternatives to licensing the proposed port are: (1) Licensing with conditions (including conditions designed to mitigate environmental impact), and (2) denying the application, which for purposes of environmental review is the ''no-action'' alternative.

Scoping Process

Public scoping is an early and open process for identifying and determining the scope of issues to be addressed in the EIS. Scoping begins with this notice, continues through the public comment period (see **DATES**), and ends when the Coast Guard has completed the following actions:

- Invites the participation of Federal, State, and local agencies, any affected Indian tribe, the applicant, and other interested persons;
- Determines the actions, alternatives, and impacts described in 40 CFR 1508.25;
- Identifies and eliminates from detailed study those issues that are not significant or that have been covered elsewhere;
- Allocates responsibility for preparing EIS components;
- Indicates any related environmental assessments or environmental impact statements that are not part of the EIS;
- Identifies other relevant environmental review and consultation requirements;
- Indicates the relationship between timing of the environmental review and other aspects of the application process; and
- At its discretion, exercises the options provided in 40 CFR 1501.7(b).

Once the scoping process is complete, the Coast Guard will prepare a draft EIS, and we will publish a **Federal Register** notice announcing its public availability. (If you want that notice to be sent to you, please contact the Coast Guard officer identified in **FOR FURTHER INFORMATION CONTACT.**) You will have an opportunity to review and comment on the draft EIS. The Coast Guard will consider those comments and then prepare the final EIS. As with the draft EIS, we will announce the availability of the final EIS and once again give you an opportunity for review and comment.

Summary of the Application

The application plan calls for the proposed deepwater port terminal to be located outside State waters in the Gulf of Mexico on the U.S. Outer Continental Shelf (OCS). Beacon Port would consist of a Main Terminal, Riser Platform, and connecting pipelines. The Main Terminal would be located approximately 50 miles (80 km) off the coast, East-Southeast of Galveston, TX (approximately 45 miles (72 km) South of High Island, TX) in OCS lease block High Island Area 27 (HIA 27). The Riser Platform would be located approximately 29 miles off the coast, South-Southeast of Johnson's Bayou, LA (approximately 27 miles South of Holly Beach, LA) in OCS lease block West Cameron 167 (WC 167). Beacon Port would serve as an LNG receiving, storage, and regasification facility. The Main Terminal would be located in water depth of approximately 65 feet (20 m).

The proposed Beacon Port Main Terminal would include: Two concrete Gravity Based Structures (GBS) that would contain the LNG storage tanks, LNG carrier berthing provisions, LNG unloading arms, low and high pressure pumps, vaporizers, metering, utility systems, general facilities and accommodations. The Main Terminal would be able to receive LNG carriers up to 253,000 cubic meters cargo capacity. LNG carrier arrival frequency would be planned to match specified terminal gas delivery rates. The terminal would have storage capacity for up to 300,000 cubic meters of LNG (150,000 cubic meters per tank) on site.

Regasification of LNG would be accomplished through the use of open rack vaporizers (ORVs). In normal operation, four pumps would operate having a combined total flow rate of approximately 167.5 million gallons per day (26,400 m^3/hr). At peak operation, five pumps would operate with a combined total flow rate of approximately 203 million gallons per day (32,000 m^3/hr).

Beacon Port proposes the installation of approximately 46 miles of offshore

natural gas transmission pipeline on the OCS. A 42-inch diameter pipeline would connect the Main Terminal with the Riser Platform. Three additional pipelines (24-inch, 20-inch, and 12.75-inch diameter) are proposed to connect the Riser Platform with existing gas distribution pipelines in the West Cameron (WC) 167 OCS block. The deepwater port would be designed to handle an average delivery of approximately 1.5 billion standard cubic feet per day (Bscfd) with a peak delivery of approximately 1.8 Bscfd.

Dated: June 7, 2005.

Raymond J. Petow,

Captain, U.S. Coast Guard, Acting Director of Standards, Marine Safety, Security, and Environmental Protection, U.S. Coast Guard.

H. Keith Lesnick,

Senior Transportation Specialist, Deepwater Ports, Program Manager, U.S. Maritime Administration.

[FR Doc. 05–11558 Filed 6–9–05; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[CGD05–05–029]

Implementation of Sector Delaware Bay

AGENCY: Coast Guard, DHS.

ACTION: Notice of organizational change.

SUMMARY: The Coast Guard announces the stand-up of Sector Delaware Bay and its subordinate entity, Sector Field Office (SFO) Atlantic City. Sector Delaware Bay is subordinate to the Fifth Coast Guard District Commander. Air Station Atlantic City remains an independent unit that is subordinate to the Fifth Coast Guard District Commander.

The Sector Delaware Bay Commander has the authority, responsibility and missions of the prior Group Philadelphia Commander, Captain of the Port (COTP), Officer in Charge, Marine Inspection (OCMI), Federal On Scene Coordinator (FOSC), Federal Maritime Security Coordinator (FMSC), and Search and Rescue Mission Coordinator (SMC). The SFO Atlantic City Commander has the authority, responsibility, and missions of the prior Group Atlantic City Commander and may be delegated Search and Rescue Mission Coordinator authority. The Coast Guard has established a continuity of operations whereby all previous practices and procedures will remain in effect until superseded by an authorized Coast Guard official and/or document.

DATES: This change was effective on March 31, 2005.

ADDRESSES: Documents indicated in this preamble as being available in the docket are part of docket CGD05–05–029 and are available for inspection or copying at Fifth District Marine Safety, 431 Crawford Street, Portsmouth, VA 23704 between 7:30 a.m. and 4:30 p.m., Monday through Friday, except Federal Holidays.

FOR FURTHER INFORMATION CONTACT: Commander Brian Hall, Fifth District Marine Safety Division at 757–398–6691.

SUPPLEMENTARY INFORMATION:

Discussion of Notice

Sector Delaware Bay is located at 1 Washington Ave., Philadelphia, PA 19147–4395. A command center supporting Sector Delaware Bay is located at Philadelphia, PA. A second command center operated by SFO Atlantic City will support the Sector Field Office and the SFO's subordinate units. Sector Delaware Bay is composed of a Response Department, Prevention Department, and Logistics Department. All existing missions and functions performed by Marine Safety Office (MSO)/Group Philadelphia and Group Atlantic City have been realigned under this new organizational structure as of March 31, 2005. MSO/Group Philadelphia and Group Atlantic City no longer exist as organizational entities. Sector Delaware Bay is responsible for all Coast Guard missions in the Philadelphia Marine Inspection Zone and Captain of the Port Zone, which are now referred to as the Delaware Bay Marine Inspection Zone and Delaware Bay Captain of the Port Zone. Group Eastern Shore retains responsibility for Search and Rescue (SAR) mission coordination for coastal Delaware and for inland portions of lower Delaware, South of Cape Henlopen at latitude 38 degrees 45 minutes N. latitude. The boundary of the Sector Delaware Bay Marine Inspection and Captain of the Port zone is as follows: ''Beginning on the New Jersey coast at 40 degrees 18 minutes N. latitude and 73 degrees 58.8 minutes W. Longitude, thence proceeds westward to 40 degrees 18 minutes N. latitude, 74 degrees 30.5 minutes W. longitude, thence north-northwesterly to the junction of the New York, New Jersey, and Pennsylvania boundaries at Tristate; thence northwesterly along the east bank of the Delaware River to 42 degrees 00 minutes N. latitude; thence west along the New York-Pennsylvania boundary to 78 degrees 55 minutes W. longitude; thence south to 41 degrees 00 minutes N. latitude; thence west to 79 degrees 00 minutes W. longitude; thence south to the Pennsylvania-Maryland boundary; thence east to the intersection of the Maryland-Delaware boundary; thence south and east along the Maryland-Delaware boundary to the sea, including Fenwick Island Light. The revised offshore boundary starts at Fenwick Island Light and proceeds east to a point at 38 degrees 26.41 minutes N. latitude and 74 degrees 26.76 minutes W. longitude; thence south eastwardly to 37 degrees 19.23 minutes N. latitude and 72 degrees 13.22 minutes W. longitude; thence east to 37 degrees 19.23 minutes and 67 degrees 54.11 minutes W. longitude; then to a point on the New Jersey coast at 40 degrees 18 minutes N. latitude and 73 degrees 58.8 minutes W. longitude.'' A chart that depicts this area can be found on the Fifth District Web page at *http://www.uscg.mil/d5/D5_Units/Sectors.htm*.

The SFO Atlantic City SMC AOR includes the waters of the Delaware Bay and those coastal offshore areas of the Sector Delaware Bay zone, except for those waters that have been assigned to Coast Guard Group Eastern Shore. The SFO Atlantic City SMC zone is as follows: ''The Sector Field Office Atlantic City Search and Rescue Mission Coordinator AOR starts on the New Jersey coast at 40 degrees 18 minutes N. latitude and 73 degrees 58.8 minutes W. longitude, thence proceeds westward to 40 degrees 18 minutes N. latitude and 74 degrees 30.5 minutes W. longitude, thence south to 39 degrees 57 minutes N. latitude and 74 degrees 30.5 minutes W. longitude, thence proceeds southwestward to 39 degrees 36 minutes N. latitude and 74 degrees 42 minutes W. longitude, thence proceeds westward to 39 degrees 30 minutes N. latitude and 75 degrees 19 minutes W. longitude, thence proceeds south to 39 degrees 19 minutes N. latitude and 75 degrees 19 minutes W. longitude, thence proceeds west to a point at 39 degrees 18.9 minutes N. latitude and 75 degrees 46.3 minutes W. longitude on the Maryland-Delaware boundary, thence proceeds south along the Maryland-Delaware boundary to a point 38 degrees 45 minutes N. latitude and 75 degrees 43.5 minutes W. longitude, thence proceeds east continuing along the Maryland-Delaware boundary to the sea, including Fenwick Island Light, thence proceeds offshore from Fenwick Island Light southeastwardly to 37 degrees 19.23 minutes N. latitude and 72 degrees 13.22 minutes W. longitude, thence proceeds east to 37 degrees 19.23

minutes N. latitude and 67 degrees 54.11 minutes W. longitude, thence proceeds northwestwardly to the start at 40 degrees 18 minutes N. latitude and 73 degrees 58.8 minutes W. longitude.''

The Sector Delaware Bay Commander is vested with all the rights, responsibilities, duties, and authority of a Group/Activities Commander and Commanding Officer, Marine Safety Office, as provided for in Coast Guard regulations, and is the successor in command to the Commanding Officer, MSO/Group Philadelphia and Commander, Group Atlantic City. The Sector Delaware Bay Commander is designated: (a) Captain of the Port (COTP) for the Delaware Bay COTP zone; (b) Federal Maritime Security Coordinator (FMSC); (c) Federal On Scene Coordinator (FOSC) for the Delaware Bay COTP zone, consistent with the National Contingency Plan; (d) Officer In Charge of Marine Inspection (OCMI) for the Delaware Bay Marine Inspection Zone and, (e) Search and Rescue Mission Coordinator (SMC). The Deputy Sector Commander is designated alternate COTP, FMSC, FOSC, SMC and Acting OCMI. The Deputy Sector Commander also assumes active search suspension (ACTSUS) authority in the absence of the Sector Commander. The Commander of SFO Atlantic City is subordinate to the Sector Commander and is vested with all the rights, responsibilities, duties, and authority of a Group Commander, which may include Search and Rescue Mission Coordinator (SMC) when delegated by the Sector Commander. In the absence of the SFO Commander, SMC authority may remain with the Acting Commander. However, active search suspension (ACTSUS) authority will revert to the Commander, Sector Delaware Bay. A continuity of operations order has been issued ensuring that all previous MSO/Group Philadelphia and Group Atlantic City practices and procedures will remain in effect until superseded by Commander, Sector Delaware Bay. This continuity of operations order addresses existing COTP regulations, orders, directives and policies.

The following information is a list of updated command titles, addresses and points of contact to facilitate requests from the public and assist with entry into security or safety zones.

Sector Delaware Bay

Commander: CAPT J. Sarubbi.

Deputy Sector Commander: CDR S. Wood.

Address: Commander, U.S. Coast Guard Sector Delaware Bay, 1 Washington Ave., Philadelphia, PA 19147–4395.

Contact: General Number: (215) 271–4940

Chief, Prevention Department: (215) 271–4859;

Chief, Response Department: (215) 271–4864;

Chief, Logistics Department: (215) 271–4912.

Sector Field Office Atlantic City

Commander: CDR T. Harrop.

Address: U.S. Coast Guard Sector Field Office Atlantic City, International Airport, Atlantic City, NJ 08401–0001.

Contact: General Number: (609) 677–2226.

Emergency search and rescue: (609) 677–2222.

Air Station Atlantic City

Commanding Officer: CAPT J. Hubbard.

Address: Commanding Officer, U.S. Coast Guard Air Station Atlantic City, International Airport, Atlantic City, NJ 08401–0001.

Contact: General Number: (609) 677–2225.

Dated: June 1, 2005.

Sally Brice-O'Hara,

Rear Admiral, U. S. Coast Guard, Commander, Fifth Coast Guard District.

[FR Doc. 05–11488 Filed 6–9–05; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4980–N–23]

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.

EFFECTIVE DATE: June 10, 2005.

FOR FURTHER INFORMATION CONTACT: Kathy Ezzell, Department of Housing and Urban Development, Room 7262, 451 Seventh Street, SW., Washington, DC 20410; telephone (202) 708–1234; TTY 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 the December 12, 1988 court order in *National Coalition for the Homeless* v. *Veterans Administration*, No. 88–2503–OG (D.D.C.), HUD publishes a notice, on a weekly basis, identifying unutilized, underutilized, excess and surplus Federal buildings and real property that HUD has reviewed for suitability for use to assist the homeless. Today's notice is for the purpose of announcing that no additional properties have been determined suitable or unsuitable this week.

Dated: June 2, 2005.

Mark R. Johnston,

Director, Office of Special Needs Assistance Programs.

[FR Doc. 05–11309 Filed 6–9–05; 8:45 am]

BILLING CODE 4210–29–M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[CA–939–04–1610–00]

Notice of Availability of the California Coastal National Monument Proposed Resource Management Plan and Final Environmental Impact Statement

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of availability.

SUMMARY: In accordance with the National Environmental Policy Act of 1969, and under the authority of the Federal Land Policy and Management Act of 1976, the Bureau of Land Management (BLM) has prepared a Proposed Resource Management Plan (RMP)/Final Environmental Impact Statement (EIS) for the California Coastal National Monument (CCNM) that is now available for public review.

DATES: BLM Planning Regulations (43 CFR 1610.5–2) state that any person who participated in the planning process, and has an interest that may be adversely affected, may protest. The protest must be filed within 30 days of the date that the Environmental Protection Agency publishes the notice of availability for the CCNM Proposed RMP/Final EIS in the **Federal Register**. Instructions for filing of protests are described in the front cover of the CCNM Proposed RMP/Final EIS and are included in the **SUPPLEMENTARY INFORMATION** section of this notice.

FOR FURTHER INFORMATION, CONTACT: Rick Hanks, California Coastal National Monument, 299 Foam Street, Monterey, California, 93940; phone: (831) 372–6115; or e-mail at: *cacnm@ca.blm.gov.*

SUPPLEMENTARY INFORMATION: The Proposed RMP would provide direction

for managing the approximate 1000 acres of offshore rocks, small islands, exposed reefs, and pinnacles that comprise the California Coastal National Monument (the Monument). The Monument was established by Presidential Proclamation on January 11, 2000, under the authority of the Antiquities Act of 1906, and directed the Secretary of the Interior to manage the Monument through the BLM. The Monument lies within the jurisdiction of 15 California counties and five BLM field offices, and at least 25 percent of the coastal portion of the mainland adjacent to the Monument is contained within the California State Parks System. Planning for the Monument officially began with a Federal Register notice on April 24, 2002 initiating scoping. The California Department of Fish and Game, the California Department of Parks and Recreation, the United States Air Force, and the Cher-Ae Heights Indian Community of the Trinidad Rancheria, a federally recognized tribe, are cooperating agencies in the development of this RMP. BLM has sought public and governmental participation in the development of this RMP and will continue to pursue partnerships in the management of the Monument. Because of the unique nature of the Monument, many governmental entities have jurisdiction over resources immediately adjacent to it and are integrally important to meeting the goals and objectives for the Monument, as established in the RMP.

Copies of the California Coastal National Monument Proposed RMP and Final EIS have been sent to affected Federal, State, and Local Government agencies and to interested parties. Copies of the Proposed RMP/Final EIS are available for public inspection at:

- California Coastal National Monument Office, 299 Foam Street, Monterey, California.
- California State Office, 2800 Cottage Way, Sacramento, California.
- Arcata Field Office, 1695 Heindon Road, Arcata, California.
- Ukiah Field Office, 2550 North State Street, Ukiah, California.
- Hollister Field Office, 20 Hamilton Court, Hollister, California.
- Bakersfield Field Office, 3801 Pegasus Drive, Bakersfield, California.
- Palm Springs Field Office, 690 West Garnet Avenue, North Palm Springs, California.
- California Desert District Office, 22835 Calle de San Juan de Los Lagos, Moreno Valley.

Interested persons may also review the Proposed RMP/Final EIS on the internet at *http://www.ca.blm.gov/pa/coastal_monument.* Comments on the Draft RMP/Draft EIS received from the public are addressed in the Proposed RMP/Final EIS. Public comments resulted in the addition of clarifying text, but did not significantly change the proposed land use decisions.

Instructions for filing a protest with the Director of the BLM regarding the Proposed RMP/Final EIS may be found at 43 CFR 1610.5. A protest may only raise those issues which were submitted for the record during the planning process. E-mail and faxed protests will not be accepted as valid protests unless the protesting party also provides the original letter by either regular or overnight mail postmarked by the close of the protest period. Under these conditions, the BLM will consider the e-mail or faxed protest as an advance copy and it will receive full consideration. If you wish to provide the BLM with such advance notification, please direct faxed protests to the attention of the BLM protest coordinator at (202) 452–5112, and e-mails to *Brenda_Hudgens-Williams@blm.gov.* Please direct the follow-up letter to the appropriate address provided below. The protest must contain:

a. The name, mailing address, telephone number, and interest of the person filing the protest.

b. A statement of the part or parts of the plan and the issue or issues being protested.

c. A copy of all documents addressing the issue(s) that the protesting party submitted during the planning process or a statement of the date they were discussed for the record.

d. A concise statement explaining why the protestor believes the State Director's decision is wrong.

All protests must be in writing and mailed to the following address:

Regular Mail: Director (210), Attention: Brenda Williams, P.O. Box 66538, Washington, DC 20035.

Overnight Mail: Director (210) Attention: Brenda Williams, 1620 L Street, NW., Suite 1075, Washington, DC 20036.

The Director will promptly render a decision on the protest. The decision will be in writing and will be sent to the protesting party by certified mail, return receipt requested. The decision of the Director shall be the final decision of the Department of the Interior.

Dated: April 1, 2005.

J. Anthony Danna,

Deputy State Director, Natural Resources.

[FR Doc. 05–11494 Filed 6–9–05; 8:45 am]

BILLING CODE 4310–40–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[ID310–1430–EU 252R, IDI–34375/34376]

Notice of Realty Action; Proposed Direct Sale of Public Lands; Jefferson County, ID

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of Realty Action.

SUMMARY: Notice is hereby given that the BLM has amended the Idaho Falls District's Medicine Lodge Resource Management Plan (RMP) to allow for the direct sale of 5.81 acres of public land in Jefferson County, Idaho to Byron and Teresa Blakely.

DATES: Comments regarding the proposed direct sale must be received within 45 days of publication of this notice in the **Federal Register**.

ADDRESSES: Written comments should be sent to Carol McCoy Brown, Field Manager, Upper Snake Field Office, 1405 Hollipark Drive, Idaho Falls, ID, 83401.

FOR FURTHER INFORMATION CONTACT: Skip Staffel, Realty Specialist, at the above address or by calling (208) 524–7562.

SUPPLEMENTARY INFORMATION: The following described lands have been examined and through the BLM land use planning process have been determined to be suitable for direct sale pursuant to Section 203 of the Federal Land Policy and Management Act of 1976 (FLPMA) (43 U.S.C. 1716). The parcel would be offered for direct sale at fair market value.

Boise Meridian, Idaho

T. 4 N., R. 40 E.,
Sec. 24, lot 18.

The area described contains approximately 5.81 acres.

The purpose of the direct sale of public land is to resolve litigation entitled *United States* v. *Byron Blakely and Teresa Blakely* (Civ. 99–339–E–BLW). The land patent, when issued, will reserve in perpetuity to the United States a conservation easement to prevent development or use of the described parcel that detracts from the conservation values of the property, which are to protect the ecological integrity of the South Fork of the Snake River, and natural habitat for wildlife, fish, and plants.

Publication of this notice in the **Federal Register** shall segregate the above described public lands from appropriation under the public land laws, including the general mining laws, except for the sale provisions of

FLPMA. The segregative effect of this notice will terminate upon issuance of patent, 270 days from the date of this publication, or in accordance with a notice of termination published in the **Federal Register**, whichever occurs first.

The appraisal report, planning document, and environmental analysis covering the proposed direct sale are available for review at the Upper Snake Field Office of the BLM. Office hours are 7:45 a. m. to 4:30 p.m., Monday through Friday, except holidays.

Dated: April 20, 2005.

Carol McCoy Brown,

Field Manger, Upper Snake Field Office.

[FR Doc. 05–11529 Filed 6–9–05; 8:45 am]

BILLING CODE 4310–22–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[WY–957–05–1420–BJ]

Notice of Filing of Plats of Survey, Wyoming

AGENCY: Bureau of Land Management, Interior.

SUMMARY: The Bureau of Land Management (BLM) has filed the plats of survey of the lands described below in the BLM Wyoming State Office, Cheyenne, Wyoming, on June 2, 2005.

FOR FURTHER INFORMATION CONTACT: Bureau of Land Management, 5353 Yellowstone Road, P.O. Box 1828, Cheyenne, Wyoming 82003.

SUPPLEMENTARY INFORMATION: These surveys were executed at the request of the Bureau of Land Management, and are necessary for the management of resources. The lands surveyed are:

The plat representing the corrective dependent resurvey of a portion of the subdivisional lines designed to restore the corners in their true original locations, Township 19 North, Range 103 West, Sixth Principal Meridian, Wyoming, was accepted June 2, 2005.

Copies of the preceding described plats and field notes are available to the public at a cost of $1.10 per page.

Dated: June 3, 2005.

John P. Lee,

Chief Cadastral Surveyor, Division of Support Services.

[FR Doc. 05–11521 Filed 6–9–05; 8:45 am]

BILLING CODE 4310–22–P

DEPARTMENT OF THE INTERIOR

National Park Service

National Register of Historic Places; Notification of Pending Nominations and Related Actions

Nominations for the following properties being considered for listing or related actions in the National Register were received by the National Park Service before May 28, 2005. Pursuant to § 60.13 of 36 CFR Part 60 written comments concerning the significance of these properties under the National Register criteria for evaluation may be forwarded by United States Postal Service, to the National Register of Historic Places, National Park Service, 1849 C St., NW., 2280, Washington, DC 20240; by all other carriers, National Register of Historic Places, National Park Service,1201 Eye St., NW., 8th floor, Washington, DC 20005; or by fax, 202–371–6447. Written or faxed comments should be submitted by June 27, 2005.

John W. Roberts, Acting Chief,

National Register/National Historic Landmarks Program.

Alabama

Dallas County

Water Avenue Historic District, Water Ave. bounded by Lauderdale, MLK Blvd., Beech Creek, Alabama R, Selma, 05000650

Etowah County

Turrentine Historic District, 300–633 Turrentine Ave., Gadsen, 05000649

Jefferson County

Southside Historic District, 2800 University Blvd., parts of 4th–7th Ave. S and 22nd–32nd St. S, Birmingham, 05000647

Mobile County

Campground, The, Martin Luther King Jr. Ave., Rylands St., St. Stephens Rd. and Ann St., Mobile, 05000648

Monroe County

New Hope Baptist Church, About 4 mi. off Monroe Cty Rd. 50 near old Natchez, Beatrice, 05000646

Talladega County

Winterboro Stagecoarch Inn, 22901 AL 21, Winteboro, 05000651

Alaska

Prince of Wales—Outer K. Borough—Census Area

Mary Island Light Station, (Light Stations of the United States MPS) East Shore, N end of Mary Island, bet. the Revillgigedo Channel and Felice Strait about 6⅜ mi. S of Revillagiedo, Ketchikan, 05000645

Colorado

Weld County

Daniels School, US 60 and Weld Cty Rd. 25, Milliken, 05000653

Yuma County

Zion, Walter and Anna, Homestead, off Cty Rd. 15, Idalia, 05000652

Florida

Lake County

Eustis Commercial Historic District, Roughly Lake Eustis, McDonald Ave., Grove St., Orange Ave., Eustis, 05000654

Louisiana

Allen Parish

St. Paul Baptist Church—Morehead School, 772 Hickory Flats Rd., Kinder, 05000686

Maryland

Kent County

Sumner, Charles, Post #25, Grand Army of the Republic, 206 S. Queen St., Chestertown, 05000655

New York

Bronx County

Morris Park Station, (New York City Subway System MPS) Under Espalanade at Bogart and Colden Ave. and Hone Ave., Bronx, 05000677

Woodlawan Station (Dual System IRT), (New York City Subway System MPS) Jct. of Bainbridge Ave. and Jerome Ave., Bronx, 05000679

Essex County

Ausable Club, 137 Ausable Rd., St. Huberts, 05000683

Greene County

St. Paul's Lutheran Church, 464 Main St., Oak Hill, 05000682

Kings County

4th Avenue Station (IND), (New York City Subway System MPS) Bet. 3rd and 4th Aves., and 10th and 11th Sts., Brooklyn, 05000673

9th Avenue Station (Dual System BRT), (New York City Subway System MPS) 38th St. and 9th Ave. near the jct. of New Utrecht Ave., Brooklyn, 05000676

Avenue U Station (Dual System BRT), (New York City Subway System MPS) Bet. Ave. U and Ave. T and 7th and 8th Sts., Brooklyn, 05000675

Bay Parkway Station (Dual System BRT), (New York City Subway System MPS) Above Bay Parkway at 86th St., Brooklyn, 05000670

New Utrecht Avenue Station (Dual System BRT), (New York City Subway System MPS) Beneath the jct. of New Utrecht Ave. with 15th Ave. and 62nd St., Brooklyn, 05000678

Substation #401, (New York City Subway System MPS) 3046 Fulton St. bet. Essex St. and Shepherd Ave., Brooklyn, 05000680

Wilson Avenue Subway Station (Dual System BMT), (New York City Subway System

MPS) Chauncey St. at Wilson Ave., Brooklyn, 05000681

Madison County

Chenango Canal Summit Level, (Historic and Engineering Resources of the Chenango Canal MPS) Along Canal Rd., Bouckville, 05000684

Nassau County

Oyster Bay Long Island Rail Road Station, Railroad Ave., Oyster Bay, 05000666

Oyster Bay Long Island Rail Road Turntable, Railroad Ave., Oyster Bay, 05000667

New York County

14th Street-Union Square Subway Station (IRT; Dual System BMT), (New York City Subway System MPS) Broadway, Fourth Ave., and E. 14th St., New York, 05000671

Beaver Building, 82–92 Beaver St., New York, 05000668

Brooklyn Bridge-City Hall Subway Station (IRT), (New York City Subway System MPS) Under Centre St. bet. Chambers and Frankfort Sts., New York, 05000674

Chambers Street Subway Station (Dual System BMT), (New York City Subway System MPS) Beneath the Municipal Building at Chambers, Centre and Duane Sts. and Lafayette Plaza, New York, 05000669

Queens County

Elmhurst Avenue Subway Station (IND), (New York City Subway System MPS) Beneath Broadway at 82nd St. and 45th Ave. and Elmhurst Ave., Queens, 05000672

Schoharie County

Forks in the Road Schoolhouse, 115 Lumber Rd., South Gilboa, 05000665

Westchester County

Marble Schoolhouse, 388 California Rd., Eastchester, 05000663

Rochelle Park—Rochelle Heights Historic District, The Circle, The Boulevard, The Serpentine, Hamilton Ave. and others, New Rochelle, 05000664

North Dakota

La Moure County

Dagen's Grocery, 616 Central Ave., Jud, 05000659

Pennsylvania

Montgomery County

Black Horse Inn, 1432 Bethlehem Pike, Flourtown, 05000685

Texas

Starr County

Mifflin Kenedy Warehouse and Old Starr County Courthouse, 200 Blk. W. Water St., Rio Grande City, 05000657

Rio Grande City Downtown Historic District, (Rio Grande City, Starr County, Texas MPS) Roughly bounded by N. Corpus, E. Wimpy, N. Avasolo and E. Mirasoles, Rio Grande City, 05000656

West Virginia

Harrison County

Edgewood Manor, 0.25 mi. N of U.S. 50 interchange on U.S. 19, Clarksburg, 05000662

Lost Creek Baltimore and Ohio Railroad Depot, Main St., Lost Creek Rd. and Cty Rte 48, Lost Creek, 05000660

Ohio County

Woodridge, 1308 Steenrod Ave., Wheeling, 05000658

Summers County

Hinton Historic District (Boundary Increase), Hill St., Hinton, 05000661

A request for REMOVAL has been made for the following resources:

Arkansas

Cleveland County

Federal Building 26 Magnolia St. Rison, 00000752

Lee County

Mison-Evans Barn 459 S. Alabama St. and U.S. 1 Bus. S. Marianna, 99001349

Prairie County

White River Bridge at DeValls Bluff (Historic Bridges of Arkansas MPS) US 70, over the White River DeValls Bluff, 90000514

A request for a MOVE has been made for the following resource:

Texas

Brazoria County

Underwood, Ammon, House Main St. Columbia, 76002011

[FR Doc. 05–11483 Filed 6–9–05; 8:45 am]

BILLING CODE 4312–51–P

INTERNATIONAL TRADE COMMISSION

[Inv. No. 337–TA–503]

In the Matter of Certain Automated Mechanical Transmission Systems for Medium-Duty and Heavy-Duty Trucks and Components Thereof; Notice of Institution of Formal Consolidated Enforcement and Advisory Opinion Proceedings

AGENCY: U.S. International Trade Commission

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has instituted a formal enforcement proceeding relating to certain remedial orders issued at the conclusion of the above-captioned investigation. The Commission has also instituted advisory opinion proceedings in the same investigation.

FOR FURTHER INFORMATION CONTACT: Rodney Maze, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street, SW., Washington, DC 20436, telephone (202) 205–3065. Copies of non-confidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street, SW., Washington, DC 20436, telephone (202) 205–2000. General information concerning the Commission may also be obtained by accessing its Internet server (*http://www.usitc.gov*). The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov*. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: This patent-based section 337 investigation was instituted by the Commission on January 7, 2004, based on a complaint filed by Eaton Corporation (''Eaton'') of Cleveland, Ohio. 67 FR 937 (January 7, 2004). The complaint, as supplemented, alleged violations of section 337 of the Tariff Act of 1930 in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain automated mechanical transmission (''AMT'') systems for medium-duty and heavy-duty trucks, and components thereof, by reason of infringement of claim 15 of U.S. patent No. 4,899,279 (''the '279 patent''); claims 1–20 of U.S. Patent No. 5,335,566 (''thee '566 patent''); claims 2–4 and 6–16 of U.S. Patent No. 5,272,939 (''the '939 patent''); claims 1–13 of U.S. Patent No. 5,624,350 (''the '350 patent''); claims 1, 3, 4, 6–9, 11, 13, 14, 16 and 17 of U.S. Patent No. 6,149,545 (''the '545 patent''); and claims 1–16 of U.S. Patent No. 6,066,071 (''the '071 patent''). The complaint and notice of investigation named three respondents ZF Meritor, LLC of Maxton, North Carolina, ZF Friedrichshafen AG of Freidrichshafen, Germany, and ArvinMeritor, Inc. (''ArvinMeritor'') of Troy, Michigan.

On January 7, 2005, the ALJ issued his final ID on violation and his recommended determination on remedy and bonding. The ALJ found a violation of section 337 by reason of infringement of claims 15 of the '279 patent by respondents. He found no violation of section 337 regarding the '566 and the '545 patents. Petitions for review were filed by Eaton, the respondents, and the commission investigative attorney

(''IA'') on January 21, 2005. All parties filed responses to the petitions on January 28, 2005.

On February 24, 2005, the Commission issued a notice indicating that it has determined not to review the ALJ's final ID on violation, thereby finding a violation of section 337. The Commission also called for briefing on the issues of remedy, the pubic interest and bonding. All parties filed timely written submissions regarding those issues. On April 7, 2005, the Commission issued a limited exclusion order and a cease and desist order covering AMT systems for medium-duty and heavy-duty trucks, and components thereof. 70 FR 19094 (April 13, 2005).

On April 21, 2005, the respondents filed a request for issuance of an advisory opinion. The IA and the complainant each filed a response on May 2, 2005, and May 4, 2005, respectively. On May 11, 2005, the complainant filed a complaint for enforcement proceedings of the Commission's remedial orders. On May 24, 2005, complaint amended its enforcement complaint.

The Commission, having examined the amended complaint for a formal enforcement proceeding filed by the complainant, and having found that the amended complaint complies with the requirements for institution of a formal enforcement proceeding, determined to institute formal enforcement proceedings to determine whether the two respondents listed below are in violation of the Commission's limited exclusion order and/or cease and desist order issued in the investigation, and what if any enforcement measures are appropriate.

The following were named as parties to the formal enforcement proceeding: (1) Complainant Eaton Corporation (2) respondent ZF Friedrichshafen AG, (3) respondent ArvinMeritor, Inc.; and (4) a Commission investigative attorney to be designated by the Director, Office of Unfair Import Investigations.

The Commission, having examined the request for an advisory opinion filed by the respondents, and having found that the request complies with the requirements for institution of advisory opinion proceedings, determined to institute advisory opinion proceedings to determine whether the importation of the respondents' redesigned FreedomLine transmission system would violate the limited exclusion order issued in the above-captioned investigation. The following were named as parties to the advisory opinion proceedings.: (1) Complainant Eaton Corporation (2) respondent ZF Friedrichshafen AG, (3) respondent ArvinMeritor, Inc.; and (4) a Commission investigative attorney to be designated by the Director, Office of Unfair Import Investigations.

The authority for the Commission's determination is contained in section 337 of the Tariff of 1930, as amended (19 U.S.C. 1337), and in sections 210.75 and 210.79 of the Commission's Rules of Practice and Procedure (19 CFR 210.75 and 210.79).

By order of the Commission.

Issued: June 6, 2005.

Marilyn R. Abbott,

Secretary to the Commission.

[FR Doc. 05–11482 Filed 6–9–05; 8:45 am]

BILLING CODE 4210–29–M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Application

Pursuant to § 1301.33(a) of Title 21 of the Code of Federal Regulations (CFR), this is notice that on April 8, 2005, Research Triangle Institute, Kenneth H. Davis Jr., Hermann Building East Institute Drive, P.O. Box 12194, Research Triangle Park, North Carolina 27709, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as a bulk manufacturer of the basic classes of controlled substances listed in Schedules I and II:

Drug	Schedule
Marihuana (7360)	I
Cocaine (9041)	II

The Institute will manufacture small quantities of cocaine derivates and marihuana derivatives for use by their customers primarily in analytical kits, reagents and preference standards.

Any other such applicant and any person who is presently registered with DEA to manufacture such a substance may file comments or objections to the issuance of the proposed registration pursuant to 21 CFR 1301.33(a).

Any such written comments or objections being sent via regular mail may be addressed, in quintuplicate, to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, Attention: DEA **Federal Register** Representative, Liaison and Policy Section (ODL); or any being sent via express mail should be sent to DEA Headquarters, Attention: DEA **Federal Register** Representative/ODL, 2401 Jefferson-Davis Highway, Alexandria, Virginia 22301; and must be filed no later than August 9, 2005.

Dated: June 2, 2005.

William J. Walker,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 05–11479 Filed 6–9–05; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Parole Commission

Record of Vote of Meeting Closure (Public Law 94–409) (5 U.S.C. Sec. 552b); Sunshine Act

I, Edward F. Reilly, Jr., Chairman of the United States Parole Commission, was present at a meeting of said Commission, which started at approximately 12 noon on Thursday, June 2, 2005, at the U.S. Parole Commission, 5550 Friendship Boulevard, 4th Floor, Chevy Chase, Maryland 20815. The purpose of the meeting was to decide case deliberations or review of two original jurisdiction cases conducting pursuant to 28 CFR 2.17 and 28 CFR 2.27. Five Commissioners were present, constituting a quorum when the vote to close the meeting was submitted.

Public announcement further describing the subject matter of the meeting and certifications of General Counsel that this meeting may be closed by vote of the Commissioners present were submitted to the Commissioners prior to the conduct of any other business. Upon motion duly made, seconded, and carried, the following Commissioners voted that the meeting be closed: Edward F. Reilly, Jr., Cranston J. Mitchell, Deborah A. Spagnoli, Isaac Fulwood, Jr., and Patricia Cushwa.

In witness whereof, I make this official record of the vote taken to close this meeting and authorize this record to be made available to the public.

Dated: June 6, 2005.

Edward F. Reilly, Jr.,

Chairman, U.S. Parole Commission.

[FR Doc. 05–11620 Filed 6–8–05; 11:01 am]

BILLING CODE 4410–01–M

DEPARTMENT OF LABOR

Office of the Secretary

Submission for OMB Review: Comment Request

June 6, 2005.

The Department of Labor (DOL) has submitted the following public information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. chapter 35). A copy of this ICR, with applicable supporting documentation, may be obtained by contacting Darrin King on 202–693–4129 (this is not a toll-free number) or e-mail: *king.darrin@dol.gov.*

Comments should be sent to Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for the Bureau of Labor Statistics (BLS), Office of Management and Budget, Room 10235, Washington, DC 20503, 202–395–7316 (this is not a toll-free number), within 30 days from the date of this publication in the **Federal Register**.

The OMB is particularly interested in comments which:

- Evaluate 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;
- Evaluate 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;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize 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 submission of responses.

Agency: Bureau of Labor Statistics.

Type of Review: Extension of a currently approved collection.

Title: Current Population Survey (CPS) Basic Labor Force.

OMB Number: 1220–0100.

Type of Response: Reporting.

Affected Public: Individuals or households.

Number of Respondents: 55,000.

Frequency: Monthly.

Annual Responses: 660,000.

Average Response Time: 7 minutes.

Estimated Annual Burden Hours: 77,000.

Total Annualized capital/startup costs: $0.

Total Annual Costs (operating/maintaining systems or purchasing services): $0.

Description: The labor force data collected in the CPS help to determine the employment situation of specific population groups as well as general trends in employment and unemployment.

Ira L. Mills,

Departmental Clearance Officer.

[FR Doc. 05–11510 Filed 6–9–05; 8:45 am]

BILLING CODE 4510–28–P

DEPARTMENT OF LABOR

Office of the Secretary

Department of Labor's Fleet Alternative Fuel Vehicle Acquisition

AGENCY: Office of the Secretary, Labor.

ACTION: Notice of availability of the Department of Labor's annual report on its alternative fuel vehicle acquisitions for fiscal year 2004. The web site also contains the Department's previous annual reports for fiscal years 1999–2003.

SUMMARY: In compliance with the Energy Policy Act of 1992 and Executive Order 13149, this notice announces the availability of the 2004 report which summarizes the U.S. Department of Labor's (DOL) compliance with the annual alternative fuel vehicle acquisition requirement for its fleet. The web site also contains the Department's previous annual reports for fiscal years 1999–2003. Additionally, the reports include data relative to the agency's effort in reducing petroleum consumption.

ADDRESSES: U.S. Department of Labor, Office of the Assistant Secretary for Administration and Management, Business Operations Center, Office of Administrative Services, 200 Constitution Avenue NW., Room S1524, Washington, DC 20210.

FOR FURTHER INFORMATION CONTACT: Al Stewart, Director of Business Operations Center at (202) 693–4021 or e-mail *Stewart.Milton@dol.gov*.

SUPPLEMENTARY INFORMATION: The Energy Policy Act of 1992 (42 U.S.C. 13211–13219) as amended by the Energy Conservation and Reauthorization Act of 1998 (Pub. L. 105–388, Section 310(b) (3) and Executive Order 13149 (April 2000) were intended to decrease the country's dependence on petroleum for transportation purposes. The Energy Policy Act of 1992 requires Federal fleets to acquire 75 percent of their new covered vehicle acquisitions as alternative fuel vehicles.

Pursuant to 42 U.S.C. 13218 of the Energy Policy Act, DOL and other covered agencies are required annually to submit to Congress reports on their Energy Policy Act's alternative fuel vehicle acquisition requirements. These reports must also be placed on an available Web site and their availability, including the Web site address, must be published in the **Federal Register**.

DOL reports for 1999, 2000, 2001, 2002, 2003, and 2004 may be accessed at the DOL Fleet Information and Regulations Web site at *http://www.dol.gov/oasam/programs/boc/epact.htm*.

Issued in Washington, DC, this 6th day of June 2005.

Patrick Pizzella,

Assistant Secretary for Administration and Management.

[FR Doc. 05–11511 Filed 6–9–05; 8:45 am]

BILLING CODE 4510–23–P

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 described classes of laborers and mechanics employed on construction projects of a similar character and in the localities specified therein.

The determination 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 of other Federal statutes 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 supersedeas decisions thereto, contain no expiration dates and are effective from the 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 ways rate and fringe benefit information for consideration be the Department. Further information and self-explanatory forms for the purpose of submitting this date 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, NW., Room S–3014, Washington, DC 20210.

Modification to General Wage Determination Decisions

The number of decisions listed to the Government Printing Office document entitled ''General Wage Determination 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 decision being modified.

Volume I

Connecticut
CT20030001 (Jun. 13, 2003)
CT20030002 (Jun. 13, 2003)
CT20030003 (Jun. 13, 2003)
CT20030004 (Jun. 13, 2003)
New Hampshire
NH20030004 (Jun. 13, 2003)
New Jersey
NJ20030003 (Jun. 13, 2003)
NJ20030005 (Jun. 13, 2003)
New York
NY20030013 (Jun. 13, 2003)

Volume II

District of Columbia
DC20030001 (Jun. 13, 2003)
DC20030003 (Jun. 13, 2003)
Maryland
MD20030002 (Jun. 13, 2003)
MD20030007 (Jun. 13, 2003)
MD20030008 (Jun. 13, 2003)
MD20030034 (Jun. 13, 2003)
MD20030035 (Jun. 13, 2003)
MD20030036 (Jun. 13, 2003)
MD20030042 (Jun. 13, 2003)
MD20030046 (Jun. 13, 2003)
MD20030047 (Jun. 13, 2003)
MD20030048 (Jun. 13, 2003)
MD20030056 (Jun. 13, 2003)
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MD20030058 (Jun. 13, 2003)
Virginia
VA20030003 (Jun. 13, 2003)
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VA20030006 (Jun. 13, 2003)
VA20030009 (Jun. 13, 2003)
VA20030012 (Jun. 13, 2003)
VA20030015 (Jun. 13, 2003)
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VA20030087 (Jun. 13, 2003)
VA20030088 (Jun. 13, 2003)
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VA20030099 (Jun. 13, 2003)

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MI20030001 (Jun. 13, 2003)
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MI20030008 (Jun. 13, 2003)
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MI20030052 (Jun. 13, 2003)
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Volume V

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MO20030001 (Jun. 13, 2003)
MO20030002 (Jun. 13, 2003)
MO20030003 (Jun. 13, 2003)
MO20030004 (Jun. 13, 2003)
MO20030006 (Jun. 13, 2003)
MO20030007 (Jun. 13, 2003)
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MO20030059 (Jun. 13, 2003)
Texas
TX20030003 (Jun. 13, 2003)
TX20030007 (Jun. 13, 2003)
TX20030010 (Jun. 13, 2003)
TX20030015 (Jun. 13, 2003)
TX20030019 (Jun. 13, 2003)
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ID20030003 (Jun. 13, 2003)
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NV20030001 (Jun. 13, 2003)
NV20030003 (Jun. 13, 2003)
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NV20030009 (Jun. 13, 2003)

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 country.

General wage determinations issued under the Davis-Bacon and related Acts are available electronically at no cost on the Government Printing Office site at *http://www.access.gpo.gov/davisbacon*. They are also available electronically by subscription to the Davis-Bacon Online Service (*http://davisbacon.fedworld.gov*) of the National Technical Information Service (NTIS) of the U.S. Department of Commerce at 1–800–363–2068. This subscription offers value-added features such as electronic delivery of modified wage decisions directly to the use's desktop, the ability to access prior wage decisions issued during the year, extensive Help desk Support, etc.

Hard-copy subscriptions may be purchased from: Superintendent of Documents; U.S. Government Printing Office, Washington, DC 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 six separate volumes, arranged by State. Subscriptions include an annual edition (issued in January or February) which includes all current general wage determinations for the State covered by each volume. Throughout the remainder of the year, regular weekly updates will be distributed to subscribers.

Signed at Washington, DC this 2 day of June 2005.

John Frank,

Acting Chief, Branch of Construction Wage Determinations.

[FR Doc. 05–11299 Filed 6–9–05; 8:45 am]

BILLING CODE 4510–27–M

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. ICR–1218–0010(2005)]

Standard on Vinyl Chloride; Extension of the Office of Management and Budget's (OMB) Approval of Information Collection (Paperwork) Requirements

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Request for public comment.

SUMMARY: OSHA solicits public comment concerning its request for an extension of the information collection requirements contained in 29 CFR 1910.1017.

DATES: Comments must be submitted by the following dates:

Hard copy: Your comments must be submitted (postmarked or received) by August 9, 2005.

Facsimile and electronic transmission: Your comments must be received by August 9, 2005.

ADDRESSES: You may submit comments, identified by OSHA Docket No. ICR–1218–0010(2005), by any of the following methods:

Regular mail, express delivery, hand delivery, and messenger service: Submit your comments and attachments to the OSHA Docket Office, Room N–2625, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210; telephone (202) 693–2350 (OSHA's TTY number is (877) 889–5627). OSHA Docket Office and Department of Labor hours are 8:15 a.m. to 4:45 p.m., ET.

Facsimile: If your comments are 10 pages or fewer in length, including attachments, you may fax them to the OSHA Docket Office at (202) 693–1648.

Electronic: You may submit comments through the Internet at *http://ecomments.osha.gov*. Follow instructions on the OSHA Web page for submitting comments.

Docket: For access to the docket to read or download comments or background materials, such as the complete Information Collection Request (ICR) (containing the Supporting Statement, OMB–83–I Form, and attachments), go to OSHA's Web page at *http://www.OSHA.gov*. In addition, the ICR, comments and submissions are available for inspection and copying at the OSHA Docket Office at the address above. You may also contact Todd Owen at the address below to obtain a copy of the ICR. For additional information on submitting comments, please see the ''Public Participation'' heading in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Todd Owen, Directorate of Standards and Guidance, OSHA Room N–3609, 200 Constitution Avenue, NW., Washington, DC 20210, telephone (202) 693–2222.

SUPPLEMENTARY INFORMATION:

I. Background

The Department of Labor, as part of its continuing efforts to reduce paperwork and respondent (i.e., employer) burden, conducts a preclearance consultation program to provide the public with an opportunity to comment on proposed and continuing information collection requirements in accordance with the Paperwork Reduction Act of 1995 (PRA–95) (44 U.S.C. 3506(c)(2)(A)).

The program ensures that information is in the desired format, reporting burden (time and costs) is minimal, collection instruments are clearly understood, and OSHA's estimate of the information collection burden is accurate. The Occupational Safety and Health Act of 1970 (the Act) (29 U.S.C. 651 *et seq.*) authorizes information collection by employers as necessary or appropriate for enforcement of the Act or for developing information regarding the causes and prevention of occupational injuries, illnesses, and accidents (29 U.S.C. 657)

On January 5, 2005, OSHA published the Standards Improvements Project—Phase II, Final rule (70 FR 1112). The final rule removed and revised provisions of standards that were outdated, duplicative, unnecessary, or inconsistent and clarified or simplified regulatory language. The final rule contained several revisions to collections of information in the Vinyl Chloride Standard.[1] These revisions included: Reducing the frequency of

[1] The Office of Management and Budget approved the reduction of 1,938 burden hours after reviewing the Information Collection Request for the Standards Improvements Project—Phase II Notice of Proposed Rulemaking, published October 31, 2002 (67 FR 66494). On January 5, 2005, when the final rule was published (70 FR 1112) documentation was submitted to OMB revising the reduction of 1,938 hours to 1,220 hours to reflect the increase in time to conduct exposure monitoring.

exposure monitoring, employee medical examinations, and updating compliance plans; allowing employers the option to post employee exposure-monitoring results instead of requiring individual notification; eliminating the need for employers to report emergencies to OSHA and to notify OSHA when establishing a regulated area. Those changes reduced paperwork burden hours while maintaining worker protection and improving consistency among standards. The following is a brief description of the current collection of information requirements contained in the Vinyl Chloride Standard.

(A) Exposure Monitoring (§ 1910.1017(d))

Paragraph 1910.1017(d)(2) requires employers to conduct exposure monitoring at least quarterly if the results show that employee exposures are above the permissible exposure limit (PEL), while those exposed at or above the Action Level (AL) must be monitored no less than semiannually. Paragraph (d)(3) requires that employers must perform additional monitoring with samples to be taken whenever there has been a change in VC production, process or control that may result in an increase in the release of VC.

(B) Written Compliance Plan (§ 1910.1017(f)(2) and (f)(3))

Paragraph (f)(2) requires employers who cannot use engineering and work-practice controls immediately to reduce employee VC exposures to a level at or below the PEL to develop and implement a plan for doing so. Paragraph (f)(3) requires employers to develop this written plan and provide it upon request for examination and copying to OSHA. These plans must be updated annually.

(C) Medical Surveillance (§ 1910.1017(k))

Paragraph (k) requires employers to develop a medical surveillance program for employees exposed to VC in excess of the action level. Examinations must be provided in accordance with this paragraph at least annually. Employers must also obtain, and provide to each employee, a copy of a physician's statement regarding the employee's suitability for continued exposure to VC, including use of protective equipment and respirators if appropriate.

(D) Recordkeeping (§ 1910.1017(m))

Employers must maintain employee exposure and medical records. The VC standard requires that employers make available monitoring, measuring, and medical records at the request of the Assistant Secretary (usually an OSHA compliance officer).

II. Special Issues for Comment

OSHA has a particular interest in comments on the following issues:

- Whether the proposed information collection requirements are necessary for the proper performance of the Agency's functions, including whether the information is useful;
- The accuracy of OSHA's estimate of the burden (time and costs) of the information collection requirements, including the validity of the methodology and assumptions used;
- The quality, utility, and clarity of the information collected; and
- Ways to minimize the burden on employers who must comply; for example, by using automated or other technological information collection and transmission techniques.

III. Proposed Actions

OSHA proposes to extend the Office of Management and Budget's (OMB) approval of the collections of information (paperwork) requirements necessitated by the Standard on Vinyl Chloride (29 CFR 1910.1017). The Agency will summarize the comments submitted in response to this notice and include this summary in its request to OMB to extend the approval of these collections of information requirements contained in the standards.

Type of Review: Extension of currently approved information collection requirements.

Title: Vinyl Chloride (29 CFR 1910.1017).

OMB Number: 1218–0010.

Affected Public: Business or other for-profits; Federal Government; State, local or tribal government.

Frequency: On occasion.

Average Time Per Response: Varies from 5 minutes (.08 hour) for employers to maintain records to 12 hours for employers to update their compliance plans.

Estimated Total Burden Hours: 1,758.

Estimated Cost (Operation and Maintenance): $113,862.

IV. Public Participation—Submission of Comments on This Notice and Internet Access to Comments and Submissions

You may submit comments and supporting materials in response to this notice by (1) hard copy, (2) FAX transmission (facsimile), or (3) electronically through the OSHA Web page. Because of security-related problems, there may be a significant delay in the receipt of comments by regular mail. Please contact the OSHA Docket Office at (202) 693–2350 (TTY (877) 889–5627) for information about security procedures concerning the delivery of submissions by express delivery, hand delivery and courier service.

All comments, submissions and background documents are available for inspection and copying at the OSHA Docket Office at the above address. Comments and submissions posted on OSHA's Web page are available at *http://www.OSHA.gov.* Contact the OSHA Docket Office for information about materials not available through the OSHA Web page and for assistance in using the Web page to locate docket submissions.

Electronic copies of this **Federal Register** notice as well as other relevant documents are available on OSHA's Web page. Since all submissions become public, private information such as social security numbers should not be submitted.

V. Authority and Signature

Jonathan L. Snare, Acting Assistant Secretary of Labor for Occupational Safety and Health, directed the preparation of this notice. The authority for this notice is the Paperwork Reduction Act of 1995 (44 U.S.C. 3506 *et seq.*), and Secretary of Labor's Order No. 5–2002 (67 FR 65008).

Signed in Washington, DC, on June 3, 2005.

Jonathan L. Snare,

Acting Assistant Secretary of Labor.

[FR Doc. 05–11579 Filed 6–9–05; 8:45 am]

BILLING CODE 4510–26–M

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. NRTL1–90]

Communication Certification Laboratory, Inc., Renewal and Expansion of Recognition

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Notice.

SUMMARY: This notice announces the Agency's final decision on the application of Communication Certification Laboratory, Inc., (CCL) for renewal of its recognition as a Nationally Recognized Testing Laboratory and for expansion of its recognition to use additional test standards under 29 CFR 1910.7.

DATES: *Recognition:* The renewal and expansion of recognition become effective on June 10, 2005.

FOR FURTHER INFORMATION CONTACT: Office of Technical Programs and Coordination Activities, NRTL Program, Occupational Safety and Health Administration, U.S. Department of Labor, 200 Constitution Avenue, NW., Room N3653, Washington, DC 20210, or phone (202) 693–2110, or phone (202) 693–2110.

SUPPLEMENTARY INFORMATION:

Notice of Final Decision

The Occupational Safety and Health Administration (OSHA) hereby gives notice of the renewal and expansion of recognition of Communication Certification Laboratory, Inc., (CCL) as a Nationally Recognized Testing Laboratory (NRTL). CCL's expansion covers the use of additional test standards. OSHA's current scope of recognition for CCL may be found in the following informational Web page: *http://www.osha.gov/dts/otpca/nrtl/ccl.html.*

OSHA recognition of an NRTL signifies that the organization has met the legal requirements in Section 1910.7 of Title 29, Code of Federal Regulations (29 CFR 1910.7). Recognition is an acknowledgment that the organization can perform independent safety testing and certification of the specific products covered within its scope of recognition and is not a delegation or grant of government authority. As a result of recognition, employers may use products ''properly certified'' by the NRTL to meet OSHA standards that require testing and certification.

The Agency processes applications by an NRTL for initial recognition or for expansion or renewal of this recognition following requirements in Appendix A to 29 CFR 1910.7. This appendix requires that the Agency publish two notices in the **Federal Register** in processing an application. In the first notice, OSHA announces the application and provides its preliminary finding and, in the second notice, the Agency provides its final decision on the application. These notices set forth the NRTL's scope of recognition or modifications of this scope.

CCL initially received OSHA recognition as a Nationally Recognized Testing Laboratory on June 21, 1991 (56 FR 28579) for a five-year period ending on June 21, 1996. CCL properly requested a renewal of recognition, and OSHA granted CCL's first renewal on April 2, 1998 (63 FR 16279) for another five-year period ending April 2, 2003.

Appendix A to 29 CFR 1910.7 stipulates that the period of recognition of an NRTL is five years and that an NRTL may renew its recognition by applying not less than nine months, nor more than one year, before the expiration date of its current recognition. NRTLs submitting requests within this allotted time period retain their recognition during OSHA's renewal process. CCL submitted a request, dated June 26, 2002 (see Exhibit 11), to renew its recognition, within the allotted time period, and retained its recognition during this renewal process. CCL also requested expansion of its recognition to include three additional test standards but amended its request to just two additional standards, which the NRTL Program staff has determined to be appropriate test standards, within the meaning of 29 CFR 1910.7(c). (The staff makes similar determinations in processing expansion requests from any NRTL.) Therefore, OSHA is approving the two test standards for the expansion, which are listed below.

For purposes of processing CCL's request, OSHA NRTL Program staff performed two on-site reviews of CCL's facility on November 18–20, 2002, and on October 29–30, 2003. In the memo for the on-site reviews (see Exhibit 12), the staff recommended CCL's renewal and its expansion to include the two test standards requested. However, the Agency delayed processing of the final notice for the renewal and expansion, in part, until it obtained certain information relative to the application. This information was obtained prior to publication of the preliminary notice.

OSHA published the notice of its preliminary findings on the renewal and expansion request in the **Federal Register** on November 24, 2004 (69 FR 68405). The notice requested submission of any public comments by December 9, 2004. OSHA did not receive any comments pertaining to the application.

Other than the preliminary notice mentioned above, the most recent notices published by OSHA for CCL's recognition covered its prior renewal, as noted above.

You may obtain or review copies of all public documents pertaining to the CCL application by contacting the Docket Office, Occupational Safety and Health Administration, U.S. Department of Labor, 200 Constitution Avenue, NW., Room N2625, Washington, DC 20210. Docket No. NRTL1–90 contains all materials in the record concerning CCL's application.

The current address of the CCL facility (site) already recognized by OSHA and included as part of the renewal is:

Communication Certification Laboratory, Inc., 1940 West Alexander Street, Salt Lake City, Utah 84119.

Final Decision and Order

NRTL Program staff has examined the application, the assessor's reports, and other pertinent information. Based upon this examination and the assessor's recommendation, OSHA finds that Communication Certification Laboratory, Inc., has met the requirements of 29 CFR 1910.7 for renewal of its recognition and for the expansion to include two additional test standards, UL 6500 and UL 61010A–1, subject to the limitations and conditions, also listed below. Pursuant to the authority in 29 CFR 1910.7, OSHA hereby renews and expands the recognition of CCL, subject to these limitations and conditions.

Limitation

OSHA limits the renewal and expansion of CCL's recognition to testing and certification of products for demonstration of conformance to the four test standards listed below.[1] OSHA has determined that the standards meet the requirements for an appropriate test standard, within the meaning of 29 CFR 1910.7(c).

UL1012 Power Units Other Than Class 2

UL 6500 Audio/Visual and Musical Instrument Apparatus for Household, Commercial, and Similar General Use

UL 60950 Information Technology Equipment

UL 61010A–1 Electrical Equipment for Laboratory Use; Part 1: General Requirements

The designation and title of the above test standards were current at the time of the preparation of the notice of the preliminary finding.

OSHA's recognition of CCL, or any NRTL, for a particular test standard is limited to equipment or materials (*i.e.*, products) for which OSHA standards require third party testing and certification before use in the workplace. Consequently, an NRTL's scope of recognition excludes any product(s) falling within the scope of a test standard for which OSHA has no

[1] Two standards, UL 1459 and UL 1950, were included in the preliminary notice on a temporary basis although they had been withdrawn by the standards developing organization. As explained in that notice, we did so pending removal or replacement of these and other withdrawn standards, at the same time, from the scope of recognition of all applicable NRTLs. The necessary **Federal Register** notice to remove or replace those test standards was published on March 8, 2005 (70 FR 11273), making it no longer necessary to temporarily include these two standards in CCL's scope.

NRTL testing and certification requirements.

Many UL test standards also are approved as American National Standards by the American National Standards Institute (ANSI). However, for convenience, we use the designation of the standards developing organization for the standard as opposed to the ANSI designation. Under our procedures, any NRTL recognized for an ANSI-approved test standard may use either the latest proprietary version of the test standard or the latest ANSI version of that standard. You may contact ANSI to find out whether or not a test standard is currently ANSI-approved.

Programs and Procedures

The renewal includes CCL's continued use of any supplemental programs for which it is approved, based upon the criteria detailed in OSHA's March 9, 1995, **Federal Register** notice on the NRTL programs (60 FR 12980). This notice lists nine (9) programs, eight of which (called the supplemental programs) an NRTL may use to control and audit, but not necessarily to generate, the data relied upon for product certification. An NRTL's initial recognition will always include the first or basic program, which requires that all product testing and evaluation be performed in-house by the NRTL that will certify the product. OSHA has already recognized CCL for the program listed below. See *http://www.osha.gov/dts/otpca/nrtl/ccl.html.*

Program 9: Acceptance of services other than testing or evaluation performed by subcontractors or agents.

OSHA developed these programs to limit how an NRTL may perform certain aspects of its work and to permit the activities covered under a program only when the NRTL meets certain criteria. In this sense, they are special conditions that the Agency places on an NRTL's recognition. OSHA does not consider these programs in determining whether an NRTL meets the requirements for recognition under 29 CFR 1910.7. However, these programs help to define the scope of that recognition.

Conditions

CCL must also abide by the following conditions of the recognition, in addition to those already required by 29 CFR 1910.7:

OSHA must be allowed access to CCL's facility and records for purposes of ascertaining continuing compliance with the terms of its recognition and to investigate as OSHA deems necessary;

If CCL has reason to doubt the efficacy of any test standard it is using under this program, it must promptly inform the test standard developing organization of this fact and provide that organization with appropriate relevant information upon which its concerns are based;

CCL must not engage in or permit others to engage in any misrepresentation of the scope or conditions of its recognition. As part of this condition, CCL agrees that it will allow no representation that it is either a recognized or an accredited Nationally Recognized Testing Laboratory (NRTL) without clearly indicating the specific equipment or material to which this recognition is tied, or that its recognition is limited to certain products;

CCL must inform OSHA as soon as possible, in writing, of any change of ownership, facilities, or key personnel, and of any major changes in its operations as an NRTL, including details;

CCL will meet all the terms of its recognition and will always comply with all OSHA policies pertaining to this recognition; and

CCL will continue to meet the requirements for recognition in all areas where it has been recognized.

Signed at Washington, DC this 31st day of May, 2005.

Jonathan L. Snare,

Acting Assistant Secretary.

[FR Doc. 05–11509 Filed 6–9–05; 8:45 am]

BILLING CODE 4510–26–P

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

National Endowment for the Arts; Arts Advisory Panel

Pursuant to Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), as amended, notice is hereby given that a meeting of the Arts Advisory Panel to the National Council on the Arts will be held by teleconference from the Nancy Hanks Center, 1100 Pennsylvania Avenue, NW., Washington, DC 20506 as follows:

National Initiatives (National Poetry Recitation Contest): June 23, 2005. This meeting, from 2 p.m. to 2:45 p.m. (E.D.T.), will be closed.

This meeting is for the purpose of Panel review, discussion, evaluation, and recommendations on financial assistance under the National Foundation on the Arts and the Humanities Act of 1965, as amended, including information given in confidence to the agency. In accordance with the determination of the Chairman of April 8, 2005, these sessions will be closed to the public pursuant to subsection (c)(6) of section 552b of Title 5, United States Code.

Further information with reference to this meeting can be obtained from Ms. Kathy Plowitz-Worden, Office of Guidelines & Panel Operations, National Endowment for the Arts, Washington, DC 20506, or call 202/682–5691.

Dated: June 6, 2005.

Kathy Plowitz-Worden,

Panel Coordinator, Panel Operations, National Endowment for the Arts.

[FR Doc. 05–11481 Filed 6–9–05; 8:45 am]

BILLING CODE 7537–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 030–32741]

Notice of Availability of Environmental Assessment and Finding of No Significant Impact for License Amendment for Central Virginia Laboratories & Consultants, Inc's Facility in Virginia Beach, VA

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of availability.

FOR FURTHER INFORMATION CONTACT: Kathy Modes, Materials Security & Industrial Branch, Division of Nuclear Materials Safety, Region I, 475 Allendale Road, King of Prussia, Pennsylvania 19406, telephone (610) 337–5251, fax (610) 337–5269; or by e-mail: kad@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Introduction

The Nuclear Regulatory Commission (NRC) is issuing a license amendment to Central Virginia Laboratories & Consultants, Inc. for Materials License No. 45–25198–01, to authorize release of its facility in Virginia Beach, Virginia, for unrestricted use. NRC has prepared an Environmental Assessment (EA) in support of this action in accordance with the requirements of 10 CFR Part 51. Based on the EA, the NRC has concluded that a Finding of No Significant Impact (FONSI) is appropriate. The amendment will be issued following the publication of this Notice.

II. EA Summary

The purpose of the action is to authorize the release of the licensee's Virginia Beach, Virginia facility for unrestricted use. Central Virginia Laboratories & Consultants, Inc. was authorized by NRC from June 16, 1992,

to use radioactive materials for environmental sample analysis purposes at the site. On November 9, 2004, Central Virginia Laboratories & Consultants, Inc. requested that NRC release the facility for unrestricted use. Central Virginia Laboratories & Consultants, Inc. has conducted surveys of the facility and provided information to the NRC to demonstrate that the site meets the license termination criteria in Subpart E of 10 CFR Part 20 for unrestricted use.

The NRC staff has prepared an EA in support of the license amendment. The facility was remediated and surveyed prior to the licensee requesting the license amendment. The NRC staff has reviewed the information and final status survey submitted by Central Virginia Laboratories & Consultants, Inc. Based on its review, the staff has determined that there are no additional remediation activities necessary to complete the proposed action. Therefore, the staff considered the impact of the residual radioactivity at the facility and concluded that since the residual radioactivity meets the requirements in Subpart E of 10 CFR Part 20, a Finding of No Significant Impact is appropriate.

III. Finding of No Significant Impact

The staff has prepared the EA (summarized above) in support of the license amendment to release the facility for unrestricted use. The NRC staff has evaluated Central Virginia Laboratories & Consultants, Inc.'s request and the results of the surveys and has concluded that the completed action complies with the criteria in Subpart E of 10 CFR Part 20. The staff has found that the radiological environmental impacts from the action are bounded by the impacts evaluated by NUREG–1496, Volumes 1–3, ''Generic Environmental Impact Statement in Support of Rulemaking on Radiological Criteria for License Termination of NRC-Licensed Facilities'' (ML042310492, ML042320379, and ML042330385). The staff also found that the non-radiological impacts are not significant. On the basis of the EA, the NRC has concluded that the environmental impacts from the action are expected to be insignificant and has determined not to prepare an environmental impact statement for the action.

IV. Further Information

Documents related to this action, including the application for the license amendment and supporting documentation, are available electronically at the NRC's Electronic Reading Room at *http://www.nrc.gov/reading-rm/adams.html*. From this site, you can access the NRC's Agencywide Document Access and Management System (ADAMS), which provides text and image files of NRC's public documents. The ADAMS accession numbers for the documents related to this Notice are: Environmental Assessment [ML051530427], letter dated November 9, 2004 [ADAMS Accession No. ML043380167], screening procedure information contained in letter dated January 17, 2005 [ADAMS Accession No. ML050340504], and survey data sent via electronic mail on February 14, 2005 [ADAMS Accession No. ML050450563]. Persons who do not have access to ADAMS or who encounter problems in accessing the documents located in ADAMS, should contact the NRC PDR Reference staff by telephone at (800) 397–4209 or (301) 415–4737, or by email to *pdr@nrc.gov*.

Documents related to operations conducted under this license not specifically referenced in this Notice may not be electronically available and/or may not be publicly available. Persons who have an interest in reviewing these documents should submit a request to NRC under the Freedom of Information Act (FOIA). Instructions for submitting a FOIA request can be found on the NRC's Web site at *http://www.nrc.gov/reading-rm/foia/foia-privacy.html*.

Dated at King of Prussia, Pennsylvania this 3rd day of June, 2005.

For the Nuclear Regulatory Commission.

James P. Dwyer,

Chief, Commercial and R&D Branch, Division of Nuclear Materials Safety Region I.

[FR Doc. 05–11496 Filed 6–9–05; 8:45 am]

BILLING CODE 7590–01–P

SMALL BUSINESS ADMINISTRATION

Privacy Act of 1974 System of Records Notice

AGENCY: U.S. Small Business Administration.

ACTION: Notice of a revised system of record.

SUMMARY: The U.S. Small Business Administration (SBA or Agency) is revising the Agency's Privacy Act System of Records for SBA's federal advisory councils. This document provides notice to the public on SBA's maintenance, use and safeguard of personal information submitted to the Agency by individuals nominated to serve as members on SBA's federal advisory councils.

DATES: This system is active July 11, 2005, unless comments are received that result in a need for modification.

ADDRESSES: Send comments to Matthew K. Becker, White House Liaison & Committee Management Officer, Office of the Administrator, U.S. Small Business Administration, 409 Third Street, SW., 7th Floor, Washington, DC 20416; Phone: (202) 205–6882; Fax: (202) 481–0906; E-mail: *matthew.becker@sba.gov.*

FOR FURTHER INFORMATION CONTACT: Donna Wood, Committee Management Specialist, (202) 619–1608; *donna.wood@sba.gov.*

SYSTEM NAME:

ADVISORY COUNCIL FILES—SBA 3.

SYSTEM LOCATION:

SBA Headquarters, 409 Third Street SW., 7th floor, Washington, DC 20416.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals currently serving as members on SBA's federal advisory councils and individuals who formerly served.

CATEGORIES OF RECORDS IN THE SYSTEM:

The system contains completed SBA Forms 898 submitted by individuals nominated to serve as members on SBA's federal advisory councils. The form requests current personal and business contact information, birthplace and date of birth, and information on the current status or history of application for SBA assistance or actual receipt of it. The system may also contain nominees' professional resumes and other correspondence.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

15 U.S.C. 637(b)(13), 648(i)(1), 657(c), Section 203, 7510–10; Pub. L. 106–50; and 44 U.S.C. 3101.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES, THESE RECORDS MAY BE USED BY, DISCLOSED OR REFERRED TO:

a. Appointed liaisons in SBA program offices, including but not limited to:

(1) Office of Government Contracting;

(2) Investment Division;

(3) Office of Financial Assistance;

(4) Office of Procurement and Grants Management;

(5) Office of Inspector General;

(6) Office of Strategic Alliances; and

(7) Office of General Counsel.

The purpose of the disclosure is to facilitate the performance of the appointed liaisons' duty to determine whether the program office has any information pertaining to a past or

current relationship between the nominee and SBA and to provide such information to the SBA's Committee Management Officer who vets nominees for conflict of interest or the appearance of conflict of interest in accordance with SOP 90 54 5, Chapter 7.

b. Member of Congress or his/her staff when the Member is inquiring on the individual's behalf, provided that the Agency determines the disclosure of the records is a use of the information contained in the records that is compatible with the purpose for which the information was collected. Under these circumstances, the Member's access rights are no greater than the individual's rights.

c. Agency volunteers, interns, grantees, experts and contractors who have been engaged by the Agency to assist in the performance of a service related to this system of records and who need access to the records in order to perform this activity. Recipients of these records shall be required to comply with the requirements of the Privacy Act of 1974, as amended, in accordance with their employment contracts.

d. The Department of Justice (DOJ) when any of the following is a party to litigation or has an interest in such litigation, and the use of such records by the DOJ is deemed by the agency to be relevant and necessary to the litigation, provided, however, that in each case, the agency determines the disclosure of the records to the DOJ is a use of the information contained in the records that is compatible with the purpose for which the records were collected:

(1) The agency, or any component thereof;

(2) Any employee of the agency in his/her official capacity;

(3) Any employee of the agency in his/her individual capacity where the DOJ has agreed to represent the employee; or

(4) The United States Government, where the agency determines that litigation is likely to affect the agency or any of its components.

e. A court, or adjudicative body, or a dispute resolution body before which any of the following is a party to litigation or has an interest in litigation, provided however, that the agency determines that the use of such records is relevant and necessary to the litigation, and that, in each case, the agency determines that disclosure of the records to a court or other adjudicative body is a use of the information contained in the records that is compatible with the purpose for which the records were collected:

(1) The agency, or any component thereof;

(2) Any employee of the agency in his or her official capacity;

(3) Any employee of the agency in his or her individual capacity where the DOJ has agreed to represent the employee; or

(4) The United States Government, where the agency determines that litigation is like to affect the agency or any of its components.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING AND DISPOSING OF RECORDS:

STORAGE:

Paper files only.

RETRIEVAL:

Records are organized according to advisory council and retrievable by the name of the current and former member.

SAFEGUARDS:

Access to SBA Headquarters is controlled and monitored by security personnel. Access to SBA program offices is limited to SBA employees with key cards. Records are maintained in locked files located in locked rooms. Access to records is limited to persons whose official duties require access to the information contained in the records.

RETENTION AND DISPOSAL:

Permanent records are maintained for 2 years and then transferred to the Federal Records Center in accordance with SOP 00 41 2, Appendix 24, 95:01.

SYSTEMS MANAGER(S) AND ADDRESS:

Committee Management Officer, Office of the Administrator, U.S. Small Business Administration, 409 Third Street SW., 7th floor, Washington, DC 20416.

NOTIFICATION PROCEDURE:

If you want to determine whether your personal information is maintained in this system of records, send a request in writing to inspect relevant records to the Committee Management Officer, Office of the Administrator, U.S. Small Business Administration, 409 Third Street SW., 7th floor, Washington, DC 20416.

ACCESS PROCEDURES:

The CMO will make relevant records available for inspection upon written request, with sufficient notice as determined by the CMO, during normal business hours.

CONTESTING PROCEDURES:

Contact the CMO using notification procedures listed above and state reason(s) for contesting his or her findings and the proposed amendment sought.

SOURCE CATEGORIES:

Record subject, Congressional offices, Agency employees, Media, Advisory Council members, **Federal Register**.

Dated: June 2, 2005.

Delorice P. Ford,

Senior Privacy Official.

Altered System of Records; Narrative Statement; U.S. Small Business Administration; Privacy Act System of Records 3

1. *Purpose.* The purpose of revising Privacy Act System of Records 3 (System) is to clarify the categories of records in the System and categories of individuals covered by the System, update policies and practices for storing, retrieving, accessing, retaining and disposing of records, and add a routine use to the System.

2. *Authority.* SBA's authority for collecting, maintaining, and using the information contained in this System is found in the following statutory provisions: 15 U.S.C. 637(b)(13), 648(i)(1), 657(c), 7105–10, Sec. 203 Pub. L. 106–50, and 44 U.S.C. 3101.

3. *Potential Effect on the Privacy of Individuals.* Categories of individuals covered by this System are individuals currently serving as members on SBA's federal advisory councils and individuals who formerly served. The additional routine use announced in this notice, which permits disclosure of information contained in this System to appointed liaisons in SBA program offices for the purpose of the vetting the individual for conflict of interest with SBA, will have a minimal effect on those categories of individuals. The SBA employees appointed to serve as liaisons are required to protect any personal information in accordance with the Privacy Act of 1974, as amended.

4. *Minimizing the Risk of Unauthorized Access to System.* SBA has taken steps to minimize the risk of unauthorized access to the System by restricting access to SBA Headquarters and SBA program offices and by securing the records with lock and key.

5. *Compatibility Requirement.* The proposed routine use of records in this System satisfies the Privacy Act's compatibility requirement, 5 U.S.C. 552a(a)(7), as it is a ''collection, or grouping of information about an individual that is maintained by an agency'' and ''contains his name, or social security number, business address, personal address, or other

identifying particular assigned to the individual.''

6. *OMB-Approved, Information Collections Contained in the System.* SBA Form 898, U.S. Small Business Administration Advisory Committee Membership—Nominee Information, OMB control number is 3245–0124.

[FR Doc. 05–11458 Filed 6–9–05; 8:45 am]

BILLING CODE 8025–01–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

Notice on Honoring Tickets of Insolvent Airlines Pursuant to the Requirements of Section 145 of the Aviation and Transportation Security Act

AGENCY: Office of the Secretary, Department of Transportation.

SUMMARY: The Department is publishing the following notice to provide guidance to the aviation industry regarding the responsibility pursuant to section 145 of the Aviation and Transportation Security Act of certain air carriers to transport under certain conditions the ticketed passengers of a carrier that has ceased operations on a particular route or routes due to bankruptcy or insolvency.

FOR FURTHER INFORMATION CONTACT: Dayton Lehman, Jr., Deputy Assistant General Counsel, or Jonathan Dols, Supervisory Trial Attorney, Office of Aviation Enforcement and Proceedings (C–70), 400 7th Street, SW., Washington, DC 20590, (202) 366–9349.

Notice

This Notice provides further guidance for airlines and the traveling public regarding the obligation of airlines under section 145 of the Aviation and Transportation Security Act, Pub. L. 107–71, 115 Stat. 645 (November 19, 2001) (''Act''), to transport passengers of airlines that have ceased operations due to insolvency or bankruptcy. In section 8404 of the Intelligence Reform and Terrorism Prevention Act of 2004 (Pub. L. 108–458 (Dec. 17, 2004)), Congress recently renewed the obligation of air carriers under section 145 to provide transportation to passengers of airlines that have ceased operations due to insolvency or bankruptcy. Prior to Congress's most recent action, the Department had issued three notices providing guidance to carriers and the public regarding section 145.[1] The purpose of this notice is to respond to the many inquiries from airlines and the public regarding section 145 received since issuance of those notices, and to provide notice that we have reconsidered our earlier estimates of the direct costs to carriers of providing alternate transportation required by section 145 and have accordingly decided that the maximum amount that a carrier may charge a passenger accommodated under the law should be greater than originally believed.

Section 145 requires, in essence, that airlines operating on the same route as an insolvent carrier that has ceased operations transport the ticketed passengers of the insolvent carrier ''to the extent practicable.'' Our earlier notices set forth, among other things, our view that, at a minimum, section 145 requires that passengers who hold valid confirmed tickets, whether paper or electronic, on an insolvent or bankrupt carrier that has ceased operations on a route be transported on a space-available basis by other carriers that operate on the route for which the passenger is ticketed. We also stated our belief that Congress did not intend to prohibit carriers from recovering from accommodated passengers the amounts associated with the actual cost of providing such transportation. We indicated at that time that we did not foresee those costs exceeding $25.00 each way, or $50.00 on a roundtrip basis. However, we also made clear that we recognized that such charges might be determined to be higher, since the cost to a carrier of complying with section 145 could be affected by a variety of factors, including the number of affected passengers, the fuel costs to carriers in effect at the time of a cessation, and the markets and itineraries involved.

Since the renewal of section 145 in December 2004, we have received many inquiries from the airline and travel agent industries, the media, and the public about various aspects of the law. These questions involve, among other issues, the amount carriers may charge displaced passengers seeking to be accommodated, as well as questions regarding section 145's applicability to international flights, code shared flights, passengers holding frequent flier tickets, and passengers whose transportation involves charter flights. As a result of these and other questions, including those raised on our own initiative, we have reviewed section 145 and are issuing this further notice, which updates and expands upon advice previously provided airlines and the public about the provision. This guidance is being provided in an attached question-and-answer format, which should assist readers in understanding the many issues involved.

Questions regarding this notice may be addressed in writing to Dayton Lehman, Deputy Assistant General Counsel, or Jonathan Dols, Supervisory Trial Attorney, Office of Aviation Enforcement and Proceedings, 400 7th St., SW., Washington, DC 20590, or they may be contacted by telephone at (202) 366–9342 or by e-mail at *dayton.lehman@dot.gov* or *jonathan.dols@dot.gov*, respectively.

Dated: June 1, 2005.

Karan Bhatia,

Assistant Secretary for Aviation and International Affairs.

Attachment to June 1, 2005, Section 145 Notice—Department of Transportation Guidance Regarding Section 145 of the Aviation and Transportation Security Act

In section 8404 of the Intelligence Reform and Terrorism Prevention Act of 2004 (Pub. L. 108–458 (Dec. 17, 2004)), Congress renewed the obligation of air carriers under section 145 of the Aviation and Transportation Security Act (Pub. L. 107–71, 115 Stat. 645 (Nov. 19, 2001) (''Act'')) to provide transportation to passengers of airlines that have ceased operations due to insolvency or bankruptcy. As amended, section 145 states in pertinent part:

(a) * * * Each air carrier that provides scheduled air transportation on a route shall provide, to the extent practicable, air transportation to passengers ticketed for air transportation on that route by any other air carrier that suspends, interrupts, or discontinues air passenger service on the route by reason of insolvency or bankruptcy of the other air carrier.

(b) * * * An air carrier is not required to provide air transportation under subsection (a) to a passenger unless that passenger makes alternative arrangements with the air carrier for such transportation within 60 days after the date on which that passenger's air transportation was suspended, interrupted, or discontinued (without regard to the originally scheduled travel date on the ticket).

(c) * * * This section does not apply to air transportation the suspension, interruption, or discontinuance of which occurs after November 19, 2005.

Questions and Answers

Question 1: What is the basic requirement of section 145?

Answer 1: At a minimum, section 145 requires that passengers holding valid confirmed tickets, whether paper or electronic, on an insolvent or bankrupt

[1] Those notices were issued on August 8, 2002, (67 FR 53035, Aug. 14, 2002) November 14, 2002, (67 FR 69805, Nov. 19, 2002) and January 23, 2003 (68 FR 4266, Jan. 28, 2003).

carrier that has ceased operations on a route by reason of that insolvency or bankruptcy be transported on a space-available basis by other carriers who operate on the route for which the passenger is ticketed.

Question 2: If a U.S. air carrier that has not yet filed for bankruptcy discontinues operating on a route for reasons of ''insolvency,'' must other air carriers operating on that route provide transportation to passengers ticketed by the insolvent air carrier?

Answer 2: Yes.

Question 3: What constitutes ''insolvency'' for purposes of section 145?

Answer 3: Insolvency is generally the inability to pay one's debts as they become due. This would probably occur with or after a bankruptcy filing, but such a filing need not necessarily occur to trigger section 145 obligations.

Question 4: Does the law apply to passengers of foreign air carriers that cease operations on international routes to or from the United States due to bankruptcy or insolvency?

Answer 4: No. The law only applies to passengers ticketed on U.S. air carriers that cease operations.

Question 5: Do foreign air carriers have any obligation under the law to accommodate passengers ticketed by U.S. carriers that have ceased operations on an international route due to bankruptcy or insolvency?

Answer 5: No. The obligation applies only to U.S. air carriers.

Question 6: Does the law provide relief for passengers who have purchased transportation on a charter flight?

Answer 6: No. We do not believe it was the intent of Congress to include charter transportation within the coverage of section 145. Although the language of section 145 does not, on its face, exclude charter passengers from its protections, the obligation to transport passengers extends only to scheduled carriers, not charter carriers, either direct or indirect. We do not believe Congress would have intended to provide protection for charter passengers without also providing a commensurate obligation on charter carriers, both direct and indirect, to accommodate the passengers of other carriers that might cease operations on a route.

In addition, there are many different types of charters that do not readily lend themselves to the type of protection we believe Congress intended under section 145, including single entity charters that might involve a company transporting its employees or a sports team, as well as on-demand air taxi charters. Moreover, some charters, such as public charters, which may be sold by charter operators that do not operate their own aircraft, and single entity charters are already subject to required financial protections in the form of surety bonds or letters of credit and/or escrow accounts for passenger funds.

We note that our Aviation Enforcement Office has in one instance advised carriers and the public of its opinion that section 145 applied to the cessation of service of a charter airline that sold transportation directly to the public. That situation involved Southeast Airlines, which ceased service on November 30, 2004. We do not expect our decision here to affect any of Southeast's passengers, whose transportation was interrupted more than 60 days ago, a period of time beyond section 145's coverage. (See section 145(b).)

Question 7: Once in bankruptcy, must an air carrier cease all operations before section 145 obligations are triggered or are section 145 obligations triggered by the cessation of operations only on a particular route or certain routes by an insolvent or bankrupt air carrier?

Answer 7: The plain language of the statute covers cessation on a route-by-route basis. However, we would expect that a carrier that ceases operations on only one or several routes would itself take steps to ensure that its ticketed passengers are transported over other routings or receive a full refund, at the passenger's choice. Moreover, if the carrier continues to hold out for sale service between the points involved, *i.e.*, in the market, the carrier would not be deemed to have ceased operations on ''that route.'' See Answer to Question 10 below.

Question 8: Because section 145 obligations are triggered by the cessation of service on one or more routes, rather than requiring a system-wide cessation of operations, are section 145 obligations triggered when a bankrupt air carrier simply reduces the number of flights it offers on a given route but does not cease all service on that route?

Answer 8: No.

Question 9: How does one determine whether a suspension, interruption, or discontinuation of service on a route is the result of bankruptcy or insolvency or of some other event not triggering section 145 obligations, such as a seasonal suspension of service or a contract dispute?

Answer 9: This will depend on the facts of each case.

Question 10: Section 145 refers to carriers that provide scheduled air transportation on the ''route'' for which a passenger is ticketed. What constitutes a ''route''?

Answer 10: Section 145 states simply that an air carrier that provides transportation on ''a route'' where service is discontinued by another air carrier due to bankruptcy or insolvency shall provide transportation on ''that route'' to passengers ticketed by the bankrupt air carrier. Since section 145 clearly is intended to help ensure that consumers' expectations are preserved and that they reach their destinations if reasonably practicable, the Department believes that Congress did not intend to limit the section 145 obligations to those carriers operating between the two points on a non-stop basis. Indeed, the service for which the passenger seeks alternate transportation may itself not have been non-stop service. On the other hand, travel on nearly every major carrier can be constructed between most pairs of points, provided one were willing to take a circuitous routing potentially involving numerous connections. We think this kind of substitute service was not what Congress intended. A carrier will be deemed to be providing transportation on ''that route'' if it holds out service between the two points to the public through its website or GDS services, regardless of the circuity involved.

For example, Carrier A discontinues service between Chicago's O'Hare Airport (ORD) and Philadelphia (PHL) due to bankruptcy. Carrier B does not offer non-stop service ORD–PHL, but does offer for sale service from ORD to PHL via Pittsburgh (PIT). Under section 145, Carrier B must provide ''to the extent practicable'' transportation ORD–PIT–PHL to passengers ticketed by Carrier A between ORD and PHL. As a counter example, Carrier A discontinues service between San Diego (SAN) and Baltimore-Washington International Airport (BWI) due to bankruptcy. Carrier B does not offer for sale any service between SAN and BWI, but a person could travel on Carrier B between SAN and BWI if he or she were willing to combine flights that operated SAN–Albuquerque (ABQ)–Houston (HOU)–Birmingham (BHM)–BWI. Under section 145, Carrier B does not have to provide transportation to passengers ticketed by Carrier A between SAN and BWI, since it does not hold out service in the SAN–BWI market.

Question 11: Under section 145, must an air carrier that offers only connecting or ''backhaul'' service on a route, transport passengers ticketed by a bankrupt air carrier on that route?

Answer 11: Yes, under section 145, if an air carrier does not hold out or operate direct service between two

cities, but holds out for sale connecting service between them, it must provide alternate transportation under section 145 to passengers ticketed by another air carrier that has discontinued its service on that route, regardless of whether the alternate transportation involves a backhaul. (See Question and Answer 10 above.)

Question 12: Under section 145, must an air carrier operating scheduled service on a route to one airport serving a city provide transportation to passengers ticketed by a bankrupt air carrier on a route to a different airport serving the same city?

Answer 12: Yes, provided that the airports are considered alternate airports for the city and the carrier from which the passenger is seeking accommodation holds out for sale service to the alternate airport. For example, Carrier A discontinues service between Los Angeles International Airport (LAX) and JFK International Airport (JFK) due to bankruptcy. Carrier B, which offers service only between (LAX) and Newark International Airport (EWR), must provide transportation from LAX to EWR to a passenger ticketed by Carrier A between LAX and JFK, since JFK and EWR are considered alternate airports serving New York City and Carrier B holds out for sale service between LAX and EWR, one of the alternate airports. We recognize that the question of whether a particular airport is considered an ''alternate airport'' may need to be determined on a case-by-case basis. Carriers should note, however, that since a primary purpose of section 145 is to assist consumers in obtaining acceptable alternate transportation and our interpretation of that provision requires transportation only on a stand-by, space-available basis, we expect carriers to take a liberal approach if this issue arises.

A carrier that serves only a portion of a passenger's itinerary and does not operate to the destination city for which the passenger is ticketed would not be obligated under section 145 to transport the passenger to another point from which the passenger might hope to obtain accommodations to his or her ultimate destination. For example, if the passenger of an insolvent or bankrupt carrier holds a ticket from Chicago to Phoenix, a carrier that does not offer service to Phoenix but does offer service to Denver is not obligated under section 145 to provide the passenger transportation to Denver in hopes that he or she can then find further transportation to Phoenix. This same result would hold if the passenger was originally ticketed from Chicago to Phoenix through Denver.

Question 13: What charge can a carrier assess for accommodating a passenger holding a ticket on a carrier that has ceased operations?

Answer 13: In our first three guidance documents, we stated that we did not believe that Congress intended to prohibit carriers from recovering from accommodated passengers the amounts associated with the actual cost of providing such transportation. We pointed out that examples of such costs include the cost of rewriting tickets, providing additional onboard meals, and the incremental fuel cost attributable to transporting an additional passenger. Based on that methodology, we found that a reasonable estimate of such costs at that time would not exceed $25 each way, regardless of the number of segments involved. Significantly, we noted that the costs of complying with section 145 may be affected by a variety of factors, including the number of passengers, the current fuel costs to carriers, and the markets and itineraries involved. We made no attempt at that time specifically to consider such factors, but indicated our willingness to do so in the future. It has been more than two years since our last notice was issued. Several carriers have requested that we reexamine this cost issue, asserting that increased costs, including that of fuel, the proven need to increase staffing to handle last-minute influxes of stand-by passengers after another carrier ceases operations, and the need to cover certain air transportation taxes, justify the Department permitting an increase in the maximum amount a carrier can charge to recover its additional expenses for providing alternate transportation under section 145. They have asked that we increase the maximum permissible amounts to $50 each way for domestic travel and travel to or from foreign points in North and Central America and the Caribbean and $125 each way for other international travel.

We have reexamined this cost issue and conclude that an increase in permissible maximum rebooking charges, including any necessary taxes and fees, to an amount of $50 each way is reasonable. Although we invite carriers to provide further comments, we do not at this time have sufficient information to justify increasing the maximum permissible amount for long-haul international travel to the maximum of $125 as requested by certain carriers. However, as described below, some governments may impose substantial taxes and fees on passengers that are collected by carriers in the price of a ticket and turned over to the government only upon travel by the passenger. Where a carrier ceases operations without having paid such amounts on behalf of the passenger, the carrier providing alternate transportation may be required to pay the tax. Under such circumstances, the $50 maximum stated above may be increased by the amount a foreign government directly assesses a carrier providing alternate transportation under section 145.

The cost of rebooking a particular passenger can vary substantially depending upon the particular circumstances involved. For example, at airports with relatively low traffic volumes, where existing alternatives can readily accommodate a small number of new passengers, the cost of doing so would be modest. On the other hand, at high traffic volume airports, particularly during the first few days following cessation of service by a major service provider at that airport, other carriers would likely have to significantly and quickly increase personnel resources in order to efficiently accommodate a surge of new passengers, resulting in considerable additional costs. These costs may be due to the need to set up new systems to verify such customers' existing ticket information and handle their stand-by status, which may require the issuance of paper tickets, a privilege for which many carriers today charge their own passengers $20 or perhaps more. These increased costs may affect carriers regardless of their size and can be even more pronounced where the carrier obligated to provide alternate transportation does not itself have a large presence at an airport involved. Such a situation will require extraordinary steps by a carrier to meet its section 145 obligation in handling the influx of passengers seeking to travel on a stand-by basis, particularly since such passengers require personal attention and handling, unlike a carrier's regular customers, who are likely to be traveling on an e-ticket and checking in over the Internet or at an unstaffed kiosk. For example, Delta Airlines was required to temporarily reassign ticket agents to its Las Vegas station from other stations after Vanguard, a much smaller carrier but one that had a relatively large presence at Las Vegas, ceased operations. Vanguard's passengers swamped the counters of Delta and other carriers seeking assistance pursuant to the requirements of section 145. Since the vast majority of passengers' itineraries will involve one or more high traffic volume airports and in light of the substantial expenses that may occur, we conclude that the increased maximum

rebooking fees of $50 discussed above are reasonable.

With regard to long-haul international routes, in their request for an increase in the maximum charge that may be assessed for accommodating a passenger under section 145, several carriers pointed to the higher costs associated with such routes due to increased expenses for fuel, meals, security, and ground handling. While this may be the case, we do not at this time have sufficient information to believe that an increase in the maximum charge to $125 is justified. However, we understand that, in certain markets, carriers may collect as part of their ticket prices departure fees that must be paid to the foreign government upon departure of the passenger. Those fees may become the responsibility of the carrier providing alternate transportation under section 145 and in such cases it is reasonable for that fee to be charged the accommodated passenger in addition to the $50 charge. As we have in the past, we invite any airline or person who believes that our estimates of the amount necessary to cover the direct costs of accommodating ticketed passengers on a space available basis are inaccurate to provide written comments and evidence of costs in support of their position.

Finally, while we are permitting the higher ceiling on fees that have been proposed, we are not mandating that any fee be charged and certainly not mandating that the ceiling fee be charged.

Question 14: If a carrier declares bankruptcy and then, after section 145 expires under its sunset clause, suspends service on a particular route, does the law apply?

Answer 14: Not if the law remains sunsetted. If, however, the law was not in effect at the time of the cessation but is later renewed, one must look to the language renewing the provision to determine if Congress intended that it not apply to cessations that have already occurred. In the absence of language to the contrary in the renewal provision, the obligation to transport qualifying passengers resumes at the time that the law goes back into effect, subject to the 60-day provision in section 145(b), without regard to when the insolvent or bankrupt carrier ceased operations.

Question 15: Does the 60-day period in which a passenger must make alternative arrangements start on the date of the bankruptcy filing or does it run from the date of the ''suspension, interruption, or discontinuance'' of service on a particular route?

Answer 15: The 60-day period runs from the date of the ''suspension, interruption, or discontinuance'' of service on a particular route. For example, if Carrier A declares bankruptcy on August 1, but continues operating its SFO-LAX service until September 1, at which time it suspends its service due to the bankruptcy, passengers ticketed by Carrier A on this route would have until October 30 to make alternative arrangements.

Question 16: Since section 145 provides a passenger 60 days in which to make alternate arrangements, does this mean that a carrier is obligated to offer standby transportation (1) on any date on which space may be available and on which the passenger desires to travel, so long as the passenger seeks such arrangements within the 60 day period, or (2) on the first date, including the passenger's original date of travel, on which space is available, or (3) only on the date the passenger was originally ticketed?

Answer 16: Although Congress was not clear on this issue, in our initial notice dated August 2, 2002, we stated that section 145 required at a minimum that a carrier is required to transport a passenger on a space-available basis on the date of travel shown on the ticket. There is some support for this interpretation, since section 145(a) applies the law's protections to ''ticketed'' passengers (on a specified route) and the 60-day provision in section 145(b) states that a passenger must make alternate arrangements ''for such transportation'' within that time frame. A strict view of the alternate transportation required to be provided as a passenger is ''ticketed'' would limit the alternate transportation to the precise date for which the passenger was originally ticketed. This could, however, produce a harsh result not intended by Congress given the consumer-oriented nature of the provision, such as could occur when a passenger is scheduled to travel on the day a carrier ceases operations and would therefore have no time to make alternate arrangement for travel that day with another carrier, or when flights of the carrier that is required to provide alternate transportation are totally booked on a particular day. On the other hand, we do not believe the provision should be read so broadly as to permit the passenger to select any travel date in the future, regardless of his or her original ticketed travel date.

We believe, therefore, that Congressional intent to assist consumers to the extent practicable is satisfied where consumers are permitted to travel on the date ticketed, or as soon thereafter as space is available, and that consumers whose ticketed date of travel is within 72 hours of the date of a cessation of operations of the carrier on which they are ticketed should be given a reasonable period of time after the cessation, not to exceed one week, in which to make such alternate arrangements.

Question 17: Must the carrier subject to a section 145 obligation provide a passenger seeking accommodation under section 145 a confirmed reservation on a flight, or can the carrier place the passenger on a ''standby'' list?

Answer 17: The carrier may place the passenger on a standby list.

Question 18: Assuming that the transportation provided under section 145 is on a standby basis and that a carrier does not normally create reservation records for standby passengers, how can an air carrier determine if a passenger had in fact made alternative arrangements with it within the 60-day window? If an air carrier cannot make such a determination, can it refuse to transport such a passenger? For example, Carrier A goes bankrupt and ceases all service on July 1. Jane Doe, who was ticketed by Carrier A on a flight scheduled for November 1, makes alternative arrangements with Carrier B on July 2 for a flight on Carrier B scheduled for November 1. Jane Doe subsequently presents herself as a standby passenger to Carrier B on November 1, but Carrier B has no record that Doe made the requisite alternative arrangements within the 60-day window since it did not create a reservation record when Jane Doe contacted it on July 2.

Answer 18: While the burden is in the first instance on a passenger to prove that he or she was ticketed for travel on the carrier that has ceased operations and has complied with the 60-day provision, after the passenger has done so, the burden of proof shifts to the carrier that is requested to provide alternate transportation if the carrier asserts that it has no obligation to transport the passenger on a space-available basis. Thus, while we do not proposed to prescribe how carriers are to meet that burden of proof, a carrier may not refuse transportation under the 60-day provision if a properly ticketed passenger asserts that he or she complied with that requirement and was promised alternate transportation on a particular day, and the carrier has no evidence to the contrary merely because the carrier elected not to institute some method of monitoring requests for alternate transportation required under section 145.

Question 19: Under section 145, can an air carrier refuse to transport an otherwise qualified passenger ticketed

by a bankrupt air carrier on the basis that the passenger was issued an ''e-ticket'' for the bankrupt carrier's flight?

Answer 19: No. However, the carrier can request reasonable proof that the passenger purchased a ticket. As stated in our prior notices, reasonable proof of purchase could be receipts and printed itineraries.

Question 20: Generally, an airline's contract of carriage states that, in the event of a change of schedule (such as a cessation of service in a market), the carrier's obligation is to reroute the passenger at no additional cost (it could be on its own service or that of another carrier) or, if the rerouting is unacceptable to the passenger, provide a full refund. Many bankruptcies involve carriers that continue to operate under Chapter 11 of the Bankruptcy Code and are authorized by the bankruptcy court to continue to operate their systems on a ''business-as-usual'' basis. In many or all such Chapter 11 cases, the bankrupt carrier petitions the court to permit refunds to pre-petition passengers to cover situations where, absent the bankruptcy, a refund would have been due. Do other air carriers have a section 145 obligation if:

- (a) A bankruptcy court permits the carrier to provide a refund but the consumer does not want the refund and also does not want to accept being rerouted on the bankrupt carrier?
- (b) Whether or not the bankruptcy court permits a refund, the bankrupt carrier is able to reroute passengers affected by a cessation of service on certain other carriers at no additional charge to the passenger in the way that the airline likely would have done through its interline agreements in the absence of the bankruptcy?

Answer 20: Under either circumstance, if the bankrupt airline can reroute the passenger to his or her destination on another of its own flights or pursuant to an agreement with another carrier, the passenger must accept this alternate arrangement, or a full refund, if applicable. (See Question and Answer numbers 7 and 10 above.)

Question 21: Can a carrier that is obligated to provide alternate transportation on a space-available basis under section 145 to passengers of a carrier that has ceased operations offer those passengers confirmed space at any price in lieu of the space-available option? What if the passenger accepts the offer and learns while checking in for the flight that standby seats are available?

Answer 21: A carrier may seek to accommodate passengers in such a manner, provided it makes clear to the passenger that the offer of a confirmed seat for the price set by the carrier is an alternative to being provided a space-available seat under section 145 and acceptance is the passenger's option. Where such an election is made by a passenger after full and accurate disclosure of his or her options under section 145, including (if known) the availability of stand-by seats, the passenger cannot later demand a refund (under terms not otherwise applicable to his or her ticket) and seek to travel under section 145 if, for example, the passenger shows up for the reserved flight and discovers stand-by seats will be available.

Questions 22 Through 28 Refer to Code Share Issues

Question 22: When considering the definition of a ''route,'' does a carrier's obligation under section 145 to provide alternate transportation apply only to routes on which it operates its own aircraft or does it also apply to code share operations where another carrier operates the aircraft?

Answer 22: The legislation does not address this issue and accordingly we believe that the answer depends on whether it is ''practicable'' for the carrier to provide alternate transportation under the code share arrangement. As stated in section 145, Congress only required alternate transportation ''to the extent practicable.'' There are several circumstances that might make it impractical for a carrier to provide transportation under section 145 on routes on which it offers only code share service. For example, a carrier's code share agreement may not give it access to the inventory of the carrier operating the aircraft nor the authority to provide stand-by service. By contrast, where the code share carrier does have access to the inventory of the operating carrier and the ability to put passengers on a standby list, it likely would be ''practicable'' to provide alternate transportation. (It appears to the Department that this would be the case in most, if not all, code share relationships between domestic regional affiliates and major carriers.)

There may be circumstances specific to code share arrangements, particularly in foreign markets, where an accommodating carrier's cost for providing transportation on its code share partner's aircraft may bear no relationship to the maximum direct costs specifically allocated to providing the transportation to that passenger. In such circumstances, the accommodating code sharing carrier may charge, in addition to the $50.00 fee, whatever additional amount is necessary to cover that specific direct transportation cost to the carrier to transport that passenger. Should the passenger dispute the charge, the carrier will have the burden of demonstrating that the additional amount charged is justified.

Question 23 (Both U.S. air carriers): Carrier A and Carrier B, both U.S. air carriers, have a code share agreement in which Carrier A operates the flight. Carrier A ceases operations by reason of bankruptcy or insolvency. What requirements exist, pursuant to section 145, with regard to passengers of Carrier A and Carrier B?

Answer 23: Other U.S. air carriers have an obligation under section 145 to provide transportation to passengers ticketed for transportation on Carrier A on its flight. Under section 145, no such obligation exists for passengers ticketed for transportation on Carrier B, because Carrier B was not the entity that ceased operations. Carrier B would, however, have obligations to the passengers holding tickets for transportation on it as set forth in its contract of carriage.

Question 24 (Both U.S. air carriers): Same as question 23, with Carrier A operating the flight, but Carrier B ceases operations due to bankruptcy.

Answer 24: Other U.S. air carriers, including Carrier A, have an obligation under section 145 to provide transportation to passengers ticketed for transportation on Carrier B. No such obligation attaches to passengers ticketed for transportation on Carrier A, because it has not ceased operations.

Question 25 (U.S. and Foreign air carriers): Carrier A, a U.S. air carrier, and Carrier B, a foreign air carrier, have a code share agreement in which U.S. Carrier A operates the flight. U.S. Carrier A ceases operations by reason of bankruptcy or insolvency. What requirements exist, pursuant to section 145, with regard to passengers of U.S. Carrier A and Foreign Carrier B?

Answer 25: Other U.S. air carriers have an obligation under section 145 to provide transportation to a passenger ticketed for transportation on a flight of U.S. Carrier A. No such obligation exists with respect to passengers ticketed for transportation on Foreign Carrier B, because section 145 applies only to passengers of a U.S. air carrier that actually ceases operations due to bankruptcy or insolvency and Carrier B is a foreign air carrier. Foreign carrier B has no obligation under section 145 to passengers ticketed for transportation on U.S. Carrier A.

Question 26 (U.S. and Foreign air carriers): Same as Question 25 except that Carrier B, the foreign air carrier, ceases operations due to bankruptcy on

a codeshare route on which U.S. Carrier A operates the flight.

Answer 26: Other U.S. air carriers, including U.S. Carrier A, have no obligation under section 145 to provide alternate transportation to passengers ticketed by Carrier B, because it is a foreign carrier. Our interpretation here with respect to U.S. Carrier A is limited to its obligation pursuant to section 145, however, and does not consider any other obligation that it may have to carry the passengers of its code share partner, Foreign Carrier B.

Question 27 (U.S. and Foreign air carriers): Carrier A, a U.S. air carrier, and Carrier B, a foreign air carrier, have a code share agreement in which Foreign Carrier B operates the flight. U.S. Carrier A ceases operations by reason of bankruptcy or insolvency. What requirements exist, pursuant to section 145, with regard to passengers of U.S. Carrier A and Foreign Carrier B?

Answer 27: Other U.S. air carriers have an obligation under section 145 to provide transportation to passengers ticketed by U.S. Carrier A, because it ceased operations on a route due to bankruptcy. Foreign Carrier B has no obligation under section 145 to transport the passengers of U.S. Carrier A, because section 145 applies only to U.S. carriers. Our interpretation here is limited to Foreign Carrier B's obligation pursuant to section 145, however, and does not consider any other obligation that it may have to carry the passengers of its code share partner, U.S. Carrier A.

Question 28 (U.S. and Foreign air carriers): Same as Question 27, except that Foreign Carrier B ceases operations due to bankruptcy on a code share route on which it operates the flight, leaving passengers ticketed by U.S. Carrier A without lift.

Answer 28: Other U.S. air carriers have no obligation under section 145 to provide transportation to passengers ticketed by U.S. Carrier A, because it has not ceased operations on a route due to insolvency or bankruptcy and no obligation to transport passengers ticketed by Foreign Carrier B, since it is a foreign carrier. Carrier A would, however, have obligations to the passengers holding tickets for transportation on it as set forth in its contract of carriage.

[FR Doc. 05–11537 Filed 6–9–05; 8:45 am]

BILLING CODE 4910–62–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

Notice of Applications for Certificates of Public Convenience and Necessity and Foreign Air Carrier Permits Filed Under Subpart B (Formerly Subpart Q) During the Week Ending May 27, 2005

The following Applications for Certificates of Public Convenience and Necessity and Foreign Air Carrier Permits were filed under subpart B (formerly subpart Q) of the Department of Transportation's Procedural Regulations (*see* 14 CFR 301.201 *et seq.*). The due date for Answers, Conforming Applications, or Motions to Modify Scope are set forth below for each application. Following the Answer period DOT may process the application by expedited procedures. Such procedures may consist of the adoption of a show-cause order, a tentative order, or in appropriate cases a final order without further proceedings.

Docket Number OST–2005–21348.

Date Filed May 26, 2005.

Due Date for Answers, Conforming Applications, or Motion to Modify Scope June 16, 2005.

Description

Application of Gulfstream Air Charter, Inc. requesting authority to operate scheduled passenger service as a commuter air carrier.

Maria Gulczewski,

Acting Program Manager, Docket Operations, Alternate Federal Register Liaison.

[FR Doc. 05–11536 Filed 6–9–05; 8:45 am]

BILLING CODE 4910–62–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket Nos. FMCSA–98–4334, FMCSA–2000–7006, FMCSA–2000–7363, FMCSA–2001–9258, FMCSA–2002–13411, FMCSA–2003–14504]

Qualification of Drivers; Exemption Applications; Vision

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of renewal of exemption; request for comments.

SUMMARY: This notice publishes the FMCSA decision to renew the exemptions from the vision requirement in the Federal Motor Carrier Safety Regulations for 31 individuals. The FMCSA has statutory authority to exempt individuals from vision standards if the exemptions granted will not compromise safety. The agency has concluded that granting these exemptions will provide a level of safety that will be equivalent to, or greater than, the level of safety maintained without the exemptions for these commercial motor vehicle (CMV) drivers.

DATES: This decision is effective June 26, 2005. Comments from interested persons should be submitted by July 11, 2005.

ADDRESSES: You may submit comments identified by DOT DMS Docket Numbers FMCSA–98–4334, FMCSA–2000–7006, FMCSA–2000–7363, FMCSA–2001–9258, FMCSA–2002–13411, and FMCSA–2003–14504, by any of the following methods:

- Web site: *http://dms.dot.gov.* Follow the instructions for submitting comments on the DOT electronic docket site.
- Fax: 1–202–493–2251.
- Mail: Docket Management Facility; U.S. Department of Transportation, 400 Seventh Street, SW., Nassif Building, Room PL–401, Washington, DC 20590–0001.
- Hand Delivery: Room PL–401 on the plaza level of the Nassif Building, 400 Seventh Street, SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays.
- Federal eRulemaking Portal: Go to *http://www.regulations.gov.* Follow the on-line instructions for submitting comments.

Instructions: All submissions must include the agency name and docket numbers for this notice. For detailed instructions on submitting comments and additional information on the rulemaking process, see the Public Participation heading of the **SUPPLEMENTARY INFORMATION** section of this document. Note that all comments received will be posted without change to *http://dms.dot.gov*, including any personal information provided. Please see the Privacy Act heading under Regulatory Notices.

Docket: For access to the docket to read background documents or comments received, go to http://dms.dot.gov at any time or to Room PL–401 on the plaza level of the Nassif Building, 400 Seventh Street, SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays.

FOR FURTHER INFORMATION CONTACT: Dr. Mary D. Gunnels, Office of Bus and Truck Standards and Operations, (202) 366–4001, FMCSA, Department of Transportation, 400 Seventh Street, SW., Washington, DC 20590–0001.

Office hours are from 8 a.m. to 5 p.m., e.t., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Public Participation: The DMS is available 24 hours each day, 365 days each year. You can get electronic submission and retrieval help guidelines under the ''help'' section of the DMS Web site. If you want us to notify you that we received your comments, please include a self-addressed, stamped envelope or postcard or print the acknowledgement page that appears after submitting comments on-line.

Privacy Act: Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review the Department of Transportation's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78) or you may visit *http://dms.dot.gov.*

Exemption Decision

Under 49 U.S.C. 31315 and 31136(e), the FMCSA may renew an exemption from the vision requirements in 49 CFR 391.41(b)(10), which applies to drivers of CMVs in interstate commerce, for a two-year period if it finds ''such exemption would likely achieve a level of safety that is equivalent to, or greater than, the level that would be achieved absent such exemption.'' The procedures for requesting an exemption (including renewals) are set out in 49 CFR part 381. This notice addresses 31 individuals who have requested renewal of their exemptions in a timely manner. The FMCSA has evaluated these 31 applications for renewal on their merits and decided to extend each exemption for a renewable two-year period. They are:

Gary A. Barrett
Donald L. Jensen
James H. Oppliger
Ivan L. Beal
Daryl A. Jester
Richard S. Rehbein
Johnny A. Beutler
Robert L. Joiner, Jr.
Bernard E. Roche
Daniel R. Brewer
James P. Jones
David E. Sanders
Lynn A. Childress
Loras G. Knebel
David B. Speller
Brett L. Condon
Larry J. Lang
Lynn D. Veach
Mark W. Coulson
Dennis D. Lesperance
Dale R. Wheeler
Thomas W. Craig
John W. Locke
Charles M. Wilkins
Myron D. Dixon
Herman G. Lovell
Michael C. Wines
Terry W. Dooley
Ronald L. Maynard
Alfred C. Jenkins
William A. Moore, Jr.

These exemptions are extended subject to the following conditions: (1) That each individual have a physical exam every year (a) by an ophthalmologist or optometrist who attests that the vision in the better eye continues to meet the standard in 49 CFR 391.41(b)(10), and (b) by a medical examiner who attests that the individual is otherwise physically qualified under 49 CFR 391.41; (2) that each individual provide a copy of the ophthalmologist's or optometrist's report to the medical examiner at the time of the annual medical examination; and (3) that each individual provide a copy of the annual medical certification to the employer for retention in the driver's qualification file and retain a copy of the certification on his/her person while driving for presentation to a duly authorized Federal, State, or local enforcement official. Each exemption will be valid for two years unless rescinded earlier by the FMCSA. The exemption will be rescinded if: (1) The person fails to comply with the terms and conditions of the exemption; (2) the exemption has resulted in a lower level of safety than was maintained before it was granted; or (3) continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31315 and 31136(e).

Basis for Renewing Exemptions

Under 49 U.S.C. 31315(b)(1), an exemption may be granted for no longer than two years from its approval date and may be renewed upon application for additional two year periods. In accordance with 49 U.S.C. 31315 and 31136(e), each of the 31 applicants has satisfied the entry conditions for obtaining an exemption from the vision requirements (63 FR 66226; 64 FR 16517; 66 FR 17994; 68 FR 35772; 65 FR 20245; 65 FR 57230; 67 FR 57266; 65 FR 45817; 65 FR 77066; 67 FR 71610; 66 FR 17743; 66 FR 33990; 67 FR 76439; 68 FR 10298; 68 FR 19598; 68 FR 33570). Each of these 31 applicants has requested timely renewal of the exemption and has submitted evidence showing that the vision in the better eye continues to meet the standard specified at 49 CFR 391.41(b)(10) and that the vision impairment is stable. In addition, a review of each record of safety while driving with the respective vision deficiencies over the past two years indicates each applicant continues to meet the vision exemption standards. These factors provide an adequate basis for predicting each driver's ability to continue to drive safely in interstate commerce. Therefore, the FMCSA concludes that extending the exemption for each renewal applicant for a period of two years is likely to achieve a level of safety equal to that existing without the exemption.

Comments

The FMCSA will review comments received at any time concerning a particular driver's safety record and determine if the continuation of the exemption is consistent with the requirements at 49 U.S.C. 31315 and 31136(e). However, the FMCSA requests that interested parties with specific data concerning the safety records of these drivers submit comments by July 11, 2005.

In the past the FMCSA has received comments from Advocates for Highway and Auto Safety (Advocates) expressing continued opposition to the FMCSA's procedures for renewing exemptions from the vision requirement in 49 CFR 391.41(b)(10). Specifically, Advocates objects to the agency's extension of the exemptions without any opportunity for public comment prior to the decision to renew, and reliance on a summary statement of evidence to make its decision to extend the exemption of each driver.

The issues raised by Advocates were addressed at length in 69 FR 51346 (August 18, 2004). The FMCSA continues to find its exemption process appropriate to the statutory and regulatory requirements.

Issued on: June 3, 2005.

Pamela M. Pelcovits,

Office Director, Policy, Plan, and Regulation.

[FR Doc. 05–11491 Filed 6–9–05; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[STB Finance Docket No. 34705]

Soo Line Railroad Company D/B/A Canadian Pacific Railway—Temporary Trackage Rights Exemption—BNSF Railway Company

BNSF Railway Company (BNSF) has agreed to grant temporary overhead

trackage rights to Soo Line Railroad Company d/b/a Canadian Pacific Railway (CPR) over BNSF's rail line between Ardoch, ND, and Erskine, MN, as follows: (1) From Ardoch at BNSF milepost 24.5 to Grand Forks, ND, at BNSF milepost 0.0, (2) from Grand Forks at BNSF milepost 109.9 to Crookston Junction, MN, at BNSF milepost 80.9, and (3) from Crookston Junction at BNSF milepost 0.0 to Erskine at BNSF milepost 31.5, a total distance of approximately 84.6 miles.[1]

The transaction was scheduled to be consummated on June 1, 2005, and the temporary trackage rights will expire on or about July 31, 2005. The purpose of the temporary trackage rights is to permit CPR to bridge its train service while the main lines of its affiliated shortline railroad are out of service due to certain programmed track, roadbed and structural maintenance.

As a condition to this exemption, any employees affected by the acquisition of the temporary trackage rights will be protected by the conditions imposed in *Norfolk and Western Ry. Co.—Trackage Rights—BN*, 354 I.C.C. 605 (1978), as modified in *Mendocino Coast Ry., Inc.—Lease and Operate,* 360 I.C.C. 653 (1980), and any employees affected by the discontinuance of those trackage rights will be protected by the conditions set out in *Oregon Short Line R. Co.—Abandonment—Goshen*, 360 I.C.C. 91 (1979).

This notice is filed under 49 CFR 1180.2(d)(8). If it 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. 34705, must be filed with the Surface Transportation Board, 1925 K Street, NW., Washington, DC 20423–0001. In addition, a copy of each pleading must be served on Thanh G. Bui, 150 South Fifth Street, Suite 2300, Minneapolis, MN 55402.

Board decisions and notices are available on our Web site at *http://www.stb.dot.gov*.

Decided: June 6, 2005.

By the Board, David M. Konschnik, Director, Office of Proceedings.

Vernon A. Williams,

Secretary.

[FR Doc. 05–11497 Filed 6–9–05; 8:45 am]

BILLING CODE 4915–01–P

[1] By amendment filed on June 2, 2005, CPR acknowledges that a .4-mile difference exists between the total mileage and the aggregate of the distances between the mileposts, but attributes that difference to inexact measurements between the mileposts.

DEPARTMENT OF THE TREASURY

Departmental Offices; Proposed Collection; Comment Request

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, 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)). Currently, the Departmental Offices within the Department of the Treasury is soliciting comments concerning the collection of Race and National Origin Identification information from job applicants.

DATES: Written comments should be received on or before July 11, 2005, to be assured of consideration.

ADDRESSES: Direct all written comments to Department of Treasury, Departmental Offices, Tracy Orrison, 1750 Pennsylvania Ave. NW., Suite 13446, Washington, DC 20006.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form(s) and instructions should be directed to Department of the Treasury, Departmental Offices, Tracy Orrison, 1750 Pennsylvania Ave, NW., Suite 13446, Washington, DC or via the Internet at *Tracy.Orrison@do.treas.gov.*

SUPPLEMENTARY INFORMATION:

Title: Race and National Origin Identification.

OMB Number: 1505–0195.

Abstract: This form will be used to collect applicant race and national origin information electronically. The data will be used to help Treasury Bureaus identify barriers to selection and determine the demographics of the applicant pool overall.

Current Actions: There are no changes being made to the form at this time.

Type of Review: Extension.

Affected Public: Individuals or households.

Estimated Number of Respondents: 160,000.

Estimated Time Per Respondent: 5 minutes.

Estimated Total Annual Burden Hours: 8,000 hours.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the 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 of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (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; and (e) estimates to capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Dated: June 7, 2005.

Carolyn Collins,

Director, Systems Development Division, HR Connect Program Office, Office of the Chief Information Officer, Department of the Treasury.

[FR Doc. 05–11520 Filed 6–9–05; 8:45 am]

BILLING CODE 4811–16–M

DEPARTMENT OF THE TREASURY

Bureau of the Public Debt

Privacy Act of 1974, as Amended; Systems of Records

AGENCY: Bureau of the Public Debt, Treasury.

ACTION: Notice of systems of records.

SUMMARY: In accordance with the requirements of the Privacy Act of 1974, as amended, 5 U.S.C. 552a, the Bureau of the Public Debt, Treasury, is publishing its Privacy Act systems of records.

SUPPLEMENTARY INFORMATION: Pursuant to the Privacy Act of 1974 (5 U.S.C. 552a) and the Office of Management and Budget (OMB) Circular No. A–130, the Bureau of the Public Debt has completed a review of its Privacy Act systems of records notices to identify minor changes that will more accurately describe these records.

The changes throughout the document are minor in nature and consist principally of changes to system locations and system manager addresses. A new location ''Avery Street Building, 320 Avery Street, Parkersburg, WV'' is added to several of the systems

of records and the address for the Washington headquarters has been changed to read ''799 9th Street, NW., Washington, DC'' throughout this Privacy Act inventory.

The following system of records has been added to the Bureau's inventory of Privacy Act notices since May 22, 2001: BPD.009—U.S. Treasury Securities Fraud Information System (Published June 9, 2003, at 68 FR 34486).

Systems Covered by This Notice

This notice covers all systems of records adopted by the Bureau up to May 2, 2005. The systems notices are reprinted in their entirety following the Table of Contents.

Dated: June 2, 2005.

Nicholas Williams,

Deputy Assistant Secretary for Headquarters Operations.

Table of Contents

BPD .001—Human Resources and Administrative Records
BPD .002—United States Savings-Type Securities
BPD .003—United States Securities (Other than Savings-Type Securities)
BPD .004—Controlled Access Security System
BPD .005—Employee Assistance Records
BPD .006—Health Service Program Records
BPD .007—Gifts to Reduce the Public Debt
BPD .008—Retail Treasury Securities Access Application
BPD .009—U.S. Treasury Securities Fraud Information System

Bureau of the Public Debt

TREASURY/BPD.001

SYSTEM NAME:

Human Resources and Administrative Records—Treasury/BPD.

SYSTEM LOCATION:

Records are maintained at the following Bureau of the Public Debt locations: 200 Third Street, Parkersburg, WV; Park Center, 90 Park Center, Parkersburg, WV; H.J. Hintgen Building, 2nd and Avery Streets, Parkersburg, WV; United Building, 5th and Avery Streets, Parkersburg, WV; Avery Street Building, 320 Avery Street, Parkersburg, WV; and 799 9th Street, NW., Washington, DC. Copies of some documents have been duplicated for maintenance by supervisors for employees or programs under their supervision. These duplicates are also covered by this system of records.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Records cover present and former employees, applicants for employment, contractors, vendors, and visitors.

CATEGORIES OF RECORDS IN THE SYSTEM:

This system of records is limited to those records Public Debt needs to function in an efficient manner and does not cover those records reported under another system of records notice.

(A) Human Resources Records: These records relate to categories such as disciplinary and adverse actions; leave and hours of duty; alternate work schedules, standards of conduct and ethics programs; indebtedness; employee suitability and security determinations; grievances; performance problems; bargaining unit matters; Federal labor relations issues; relocation notices; outside employment; recruitment; placement; merit promotion; special hiring programs, including Summer Employment, Veterans Readjustment, Career Development for Lower Level Employees (CADE), Student Employment Programs; position classification and management; special areas of pay administration, including grade and pay retention, premium pay, scheduling of work, performance management and recognition; training and employee development programs; incentive awards; benefits and retirement programs; personnel and payroll actions; insurance; worker's and unemployment compensation; employee orientation; retirement; accident reports; and consolidation of personnel/program efforts among offices.

(B) Equal Employment Opportunity Records: These are records of informal EEO complaints and discussions which have not reached the level of formal complaints. After 30 days these records are destroyed or incorporated in a formal complaint file. Formal complaints are handled by the Treasury Department's Regional Complaints Center. Copies of formal complaint documents are sometimes maintained by Public Debt's EEO Office.

(C) Administrative Services Records: These records relate to administrative support functions including motor vehicle operation, safety, access to exterior and interior areas, contract guard records, offense/incident reports, accident reports, and security determinations.

(D) Procurement Records: These records relate to contractors/vendors if they are individuals; purchase card holders, including the name, social security number and credit card number for employees who hold Government-use cards; procurement integrity certificates, containing certifications by procurement officials that they are familiar with the Federal Procurement Policy Act.

(E) Financial Management Records: These records relate to government travel, vendor accounts, other employee reimbursements, interagency transactions, employee pay records, vendor registration data, purchase card accounts and transactions, and program payment agreements.

(F) Retiree Mailing Records: These records contain the name and address furnished by Public Debt retirees requesting mailings of newsletters and other special mailings.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 301; 31 U.S.C. 321.

PURPOSE(S):

These records are collected and maintained to document various aspects of a person's employment with the Bureau of the Public Debt and to assure the orderly processing of administrative actions within the Bureau.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

These records may be disclosed to:

(1) The Office of Personnel Management, the Merit Systems Protection Board, the Equal Employment Opportunity Commission, and the Federal Labor Relations Authority upon authorized request;

(2) Other Federal, State, or local agencies, such as a State employment compensation board or housing administration agency, so that the agency may adjudicate an individual's eligibility for a benefit, or liability in such matters as child support;

(3) Creditors, potential creditors, landlords, and potential landlords when they request employment data or salary information for purposes of processing the employee's loan, mortgage, or apartment rental application (when information is requested by telephone, only verification of information supplied by the caller will be provided);

(4) Next-of-kin, voluntary guardians, and other representative or successor in interest of a deceased or incapacitated employee or former employee;

(5) Unions recognized as exclusive bargaining representatives under 5 U.S.C. chapter 71, arbitrators, and other parties responsible for the administration of the Federal labor-management program if needed in the performance of their authorized duties;

(6) Private creditors for the purpose of garnishing wages of an employee if a debt has been reduced to a judgment;

(7) Authorized Federal and non-Federal entities for use in approved computer matching efforts, limited to those data elements considered

necessary in making a determination of eligibility under particular benefit programs administered by those agencies or entities, to improve program integrity, and to collect debts and other monies owed to those agencies or entities or to the Bureau of the Public Debt;

(8) Contractors of the Bureau for the purpose of processing personnel and administrative records;

(9) Other Federal, State, or local agencies in connection with the hiring or retention of an individual, the issuance of a security clearance, the conducting of a security or suitability investigation of an individual, the issuance of a license, contract, grant, or other benefit;

(10) Congressional offices in response to an inquiry made at the request of the individual to whom the record pertains;

(11) Other Federal agencies to effect salary or administrative offset for the purpose of collecting a debt, except that addresses obtained from the Internal Revenue Service shall not be disclosed to other agencies;

(12) Consumer reporting agencies, including mailing addresses obtained from the Internal Revenue Service to obtain credit reports;

(13) Debt collection agencies, including mailing addresses obtained from the Internal Revenue Service, for debt collection services;

(14) Appropriate Federal, State, local, or foreign agencies responsible for investigating or prosecuting the violations of, or for enforcing or implementing a statute, rule, regulation, order, or license, where the disclosing agency becomes aware of an indication of a violation or potential violation of civil or criminal law or regulation;

(15) A court, magistrate, or administrative tribunal in the course of presenting evidence, including disclosures to opposing counsel or witnesses in the course of civil discovery, litigation, or settlement negotiations or in connection with criminal law proceedings or in response to a subpoena;

(16) Third parties during the course of an investigation to the extent necessary to obtain information pertinent to the investigation.

DISCLOSURE TO CONSUMER REPORTING AGENCIES:

Debtor information is also furnished, in accordance with 5 U.S.C. 552a(b)(12) and section 3 of the Debt Collection Act of 1982, to consumer reporting agencies to encourage repayment of an overdue debt.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records in this system are stored on paper, microform, or in electronic media.

RETRIEVABILITY:

By name, social security number, or other assigned identifier.

SAFEGUARDS:

These records are maintained in controlled access areas. Identification cards are verified to ensure that only authorized personnel are present. Electronic records are protected by restricted access procedures, including the use of passwords and sign-on protocols which are periodically changed. Only employees whose official duties require access are allowed to view, administer, and control these records. Copies of records maintained on computer have the same limited access as paper records.

RETENTION AND DISPOSAL:

Records are maintained in accordance with National Archives and Records Administration retention schedules. Paper and microform records ready for disposal are destroyed by shredding or maceration. Records in electronic media are electronically erased using accepted techniques.

SYSTEM MANAGER(S) AND ADDRESS:

(A) Human Resources Records: Directors, Human Resources Division and Human Resources Operations Division.

(B) Equal Employment Opportunity Records: Equal Employment Opportunity Manager, 200 Third Street, Parkersburg, WV 26106–1328.

(C) Administrative Services Records: Director, Administrative Services Division, 200 Third Street, Parkersburg, WV 26106–1328.

(D) Procurement Records: Director, Division of Procurement, United Building, 5th and Avery Streets, Parkersburg, WV 26106–1328.

(E) Financial Management Records: Director, Accounting Services Division, 200 3rd Street, UNB 6th Floor, Parkersburg, WV 26106–1328.

(F) Retiree Mailing Records: Director, Division of Support Services, 200 Third Street, Parkersburg, WV 26106–1328.

NOTIFICATION PROCEDURE:

Individuals may submit their requests for determination of whether the system contains records about them or for access to records as provided under ''Records Access Procedures.'' Requests must be made in compliance with the applicable regulations (31 CFR part 1, subpart C). Requests which do not comply fully with these procedures may result in noncompliance with the request, but will be answered to the extent possible.

RECORD ACCESS PROCEDURES:

(1) A request for access to records must be in writing, signed by the individual concerned, identify the system of records, and clearly indicate that the request is made pursuant to the Privacy Act of 1974. If the individual is seeking access in person, identity may be established by the presentation of a single official document bearing the individual's photograph or by the presentation of two items of identification without the photograph but showing a name and signature. If the individual is seeking access by mail, identity may be established by presenting a signature, address, and one other identifier such as a photocopy of an official document bearing the individual's signature. The Bureau of the Public Debt reserves the right to require additional verification of an individual's identity.

(2) Submit requests to the appropriate office as shown under ''System Manager and Address'' above.

(3) The request must state whether the requester wishes to be notified that the record exists or desires to inspect or obtain a copy of the record. If a copy of the record is desired, the requester must agree to pay the fees for copying the documents in accordance with 31 CFR 1.26(d)(2)(ii).

CONTESTING RECORD PROCEDURES:

Initial amendment requests: (1) A request by an individual contesting the content of records or for correction of records must be in writing, signed by the individual involved, identify the system of records, and clearly state that the request is made pursuant to the Privacy Act of 1974. If the request is made in person, identity may be established by the presentation of a single official document bearing the individual's photograph or by the presentation of two items of identification without the photograph but instead showing a name and signature. If the request is made by mail, identity may be established by the presentation of a signature, address, and one other identifier such as a photocopy of an official document bearing the individual's signature. The Bureau of the Public Debt reserves the right to require additional verification of an individual's identity.

(2) Submit requests to the appropriate office as shown under ''System Manager and Address'' above.

(3) The request must specify:

(a) The dates of records in question,

(b) The specific records alleged to be incorrect,

(c) The correction requested, and

(d) The reasons.

(4) The request must include available evidence in support of the request.

Appeals from an initial denial of a request for correction of records:

(1) An appeal from an initial denial of a request for correction of records must be in writing, signed by the individual involved, identify the system of records, and clearly state that it is made pursuant to the Privacy Act of 1974. If the individual is making an appeal in person, identity may be established by the presentation of a single official document bearing the individual's photograph or by the presentation of two items of identification without the photograph but showing a name and signature. If the individual is making an appeal by mail, identity may be established by the presentation of a signature, address, and one other identifier such as a photocopy of an official document bearing the individual's signature. The Bureau of the Public Debt reserves the right to require additional verification of an individual's identity.

(2) Appellate determinations will be made by the Commissioner of the Public Debt or the delegate of such officer. Appeals should be addressed to, or delivered personally to: Chief Counsel, Bureau of the Public Debt, 799 9th Street, NW, Room 501, Washington, DC 20239–0001 (or as otherwise provided for in the applicable appendix to 31 CFR part 1, subpart C), within 35 days of the individual's receipt of the initial denial of the requested correction.

(3) An appeal must be marked ''Privacy Act Amendment Appeal'' and specify:

(a) The records to which the appeal relates,

(b) The date of the initial request made for correction of the records, and

(c) The date the initial denial of the request for correction was received.

(4) An appeal must also specify the reasons for the requester's disagreement with the initial denial of correction and must include any applicable supporting evidence.

RECORD SOURCE CATEGORIES:

Information in this system of records is provided by the subject of the record, authorized representatives, supervisor, employers, medical personnel, other employees, other Federal, State, or local agencies, and commercial entities.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

TREASURY/BPD.002

SYSTEM NAME:

United States Savings-Type Securities-Treasury/BPD.

SYSTEM LOCATION:

Bureau of the Public Debt, Washington, DC, and Parkersburg, WV. Federal Reserve Banks and Branches located at: Buffalo, NY; Kansas City, MO; Minneapolis, MN; Pittsburgh, PA, and Richmond, VA.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Present and former owners of, claimants to, persons entitled to, and inquirers concerning United States savings-type securities and interest thereon, including, but not limited to, United States Savings Bonds, Savings Notes, Retirement Plan Bonds, and Individual Retirement Bonds.

CATEGORIES OF RECORDS IN THE SYSTEM:

(1) Issuance: Records relating to registration, issuance, and correspondence in connection with issuance of savings-type securities. This category includes records of current income savings bonds processed under an automated system which will permit access by selected Federal Reserve Banks and Branches.

(2) Holdings: Records documenting ownership, status, payments by date and account numbers, and inscription information; interest activity; correspondence in connection with notice of change of name and address; non-receipt or over- or underpayments of interest and principal; and numerical registers of ownership. Such records include information relating to savings-type securities held in safekeeping in conjunction with the Department's program to deliver such securities to the owners or persons entitled. This category includes records of current income savings bonds processed under an automated system which will permit access by selected Federal Reserve Banks and Branches.

(3) Transactions (redemptions, payments, and reissues): Records, which include securities transaction requests; interest activity; legal papers supporting transactions; applications for disposition or payment of securities and/or interest thereon of deceased or incapacitated owners; records of retired securities; and payment records. This category includes records of current income savings bonds processed under an automated system which will permit access by selected Federal Reserve Banks and Branches.

(4) Claims: Records including correspondence concerning lost, stolen, destroyed, or mutilated savings-type securities; bonds of indemnity; legal documents supporting claims for relief; and records of caveats entered.

(5) Inquiries: Records of correspondence with individuals who have requested information concerning savings-type securities and/or interest thereon.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 301; 31 U.S.C. 3101, *et seq.*

PURPOSES:

Information in this system of records is collected and maintained to enable Public Debt and its agents to issue savings bonds, to process transactions, to make payments, and to identify owners and their accounts.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

These records may be disclosed to:

(1) Agents or contractors of the Department for the purpose of administering the public debt of the United States;

(2) Next-of-kin, voluntary guardian, legal representative or successor in interest of a deceased or incapacitated owner of securities and others entitled to the reissue, distribution, or payment for the purpose of assuring equitable and lawful disposition of securities and interest;

(3) Either coowner for bonds registered in that form or to the beneficiary for bonds registered in that form, provided that acceptable proof of death of the owner is submitted;

(4) The Internal Revenue Service for the purpose of facilitating collection of the tax revenues of the United States;

(5) The Department of Justice in connection with lawsuits to which the Department of the Treasury is a party to trustees in bankruptcy for the purpose of carrying out their duties;

(6) The Veterans Administration and selected veterans' publications for the purpose of locating owners or other persons entitled to undeliverable bonds held in safekeeping by the Department;

(7) Other Federal agencies to effect salary or administrative offset for the purpose of collecting debts;

(8) A consumer reporting agency, including mailing addresses obtained from the Internal Revenue Service, to obtain credit reports;

(9) A debt collection agency, including mailing addresses obtained from the Internal Revenue Service, for debt collection services;

(10) Contractors conducting Treasury-sponsored surveys, polls, or statistical analyses relating to the marketing or administration of the public debt of the United States;

(11) Appropriate Federal, State, local, or foreign agencies responsible for investigating or prosecuting the violations of, or for enforcing or implementing, a statute, rule, regulation, order, or license;

(12) A court, magistrate, or administrative tribunal in the course of presenting evidence, including disclosures to opposing counsel or witnesses in the course of civil discovery, litigation, or settlement negotiations or in connection with criminal law proceedings or in response to a subpoena;

(13) A Congressional office in response to an inquiry made at the request of the individual to whom the record pertains;

(14) Disclose through computer matching information on individuals owing debts to the Bureau of the Public Debt to other Federal agencies for the purpose of determining whether the debtor is a Federal employee or retiree receiving payments which may be used to collect the debt through administrative or salary offset;

(15) Disclose through computer matching information on holdings of savings-type securities to requesting Federal agencies under approved agreements limiting the information to that which is relevant in making a determination of eligibility for Federal benefits administered by those agencies; and

(16) Disclose through computer matching, information on individuals with whom the Bureau of the Public Debt has lost contact, to other Federal agencies for the purpose of utilizing letter forwarding services to advise these individuals that they should contact the Bureau about returned payments and/or matured, unredeemed securities.

DISCLOSURES TO CONSUMER REPORTING AGENCIES:

Debtor information is also furnished, in accordance with 5 U.S.C. 552a(b)(12) and section 3 of the Debt Collection Act of 1982, to consumer reporting agencies to encourage repayment of an overdue debt.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records in this system are stored on paper, microform, or in electronic media.

RETRIEVABILITY:

Information can be retrieved alphabetically by name, address, and period of time the security was issued, by bond serial numbers, other assigned identifier, or, in some cases, numerically by social security number. In the case of securities, except Series G savings bonds, registered in more than one name, information relating thereto can be retrieved only by the names, or, in some cases, the social security number of the registrants, primarily the registered owners or first-named coowners. In the case of gift bonds inscribed with the social security number of the purchaser, bonds are retrieved under that number, or by bond serial number.

SAFEGUARDS:

Information is contained in secure buildings or in areas which are occupied either by officers and responsible employees of Public Debt who are subject to personnel screening procedures and to the Treasury Department Code of Conduct or by agents of Public Debt who are required to maintain proper control over records while in their custody. Additionally, since in most cases, numerous steps are involved in the retrieval process, unauthorized persons would be unable to retrieve information in meaningful form. Information stored in electronic media is safeguarded by automatic data processing security procedures in addition to physical security measures. Additionally, for those categories of records stored in computers with online terminal access, the information cannot be accessed without proper passwords and preauthorized functional capability.

RETENTION AND DISPOSAL:

Records of holdings, forms, documents, and other legal papers which constitute the basis for transactions subsequent to original issue are maintained for such time as is necessary to protect the legal rights and interests of the United States Government and the persons affected, or otherwise until they are no longer historically significant. Other records are disposed of at varying intervals in accordance with records retention schedules reviewed and approved by the National Archives and Records Administration (NARA). Paper and microform records ready for disposal are destroyed by shredding or maceration. Records in electronic media are electronically erased using accepted techniques.

SYSTEM MANAGER(S) AND ADDRESS:

Assistant Commissioner, Securities Operations, Parkersburg, WV 26106–1328.

NOTIFICATION PROCEDURE:

Individuals may submit their requests for determination of whether the system contains records about them or for access to records as provided under ''Records Access Procedures.'' Requests must be made in compliance with the applicable regulations (31 CFR part 1, subpart C). Requests which do not comply fully with these procedures may result in noncompliance with the request, but will be answered to the extent possible.

RECORD ACCESS PROCEDURES:

(1) A request for access to records must be in writing, signed by the individual concerned, identify the system of records, and clearly indicate that the request is made pursuant to the Privacy Act of 1974. If the individual is seeking access in person, identity may be established by the presentation of a single official document bearing the individual's photograph or by the presentation of two items of identification without the photograph but showing a name and signature. If the individual is seeking access by mail, identity may be established by presenting a signature, address, and one other identifier such as a photocopy of an official document bearing the individual's signature. The Bureau of the Public Debt reserves the right to require additional verification of an individual's identity.

(2) The request must state whether the requester wishes to be notified that the record exists or desires to inspect or obtain a copy of the record. If a copy of the record is desired, the requester must agree to pay the fees for copying the documents in accordance with 31 CFR 1.26(d)(2)(ii).

(3) Requests by individuals about securities they own:

(a) For current income savings bonds: Individuals may make inquiries at a Federal Reserve Bank or Branch or directly to the Bureau of the Public Debt, Investor Services, Current Income Services Division, Parkersburg, WV 26106–1328. If the particular Federal Reserve Bank or Branch cannot access the particular record, the individual will be advised to contact the Bureau of the Public Debt. Individuals must provide sufficient information, including their address and social security number, to identify themselves as owner or coowner of the securities. They should provide the complete bond serial numbers, including alphabetic prefixes

and suffixes, if known. Otherwise, the series, approximate date, form of registration, and, except for Series G Savings Bonds registered in coownership form, the names and social security numbers of all persons named in the registration should be provided. If a Case Identification Number is known, that should be provided.

(b) For all other types of securities covered by this system of records: Individuals should contact the following: Bureau of the Public Debt, Investor Services, Accrual Services Division, Parkersburg, WV 26106–1328. Individuals should provide sufficient information, including their address and social security number, to identify themselves as owner or coowner of the securities. Individuals must provide sufficient information to identify the securities, such as type or series of security, approximate date of issue, serial number, form of registration, and the name and social security number of the first-named coowner, or in the case of gift bonds the social security number of the purchaser if that number was used.

(4) Requests by anyone other than individuals named on securities must contain sufficient information to identify the securities; this would include type or series of securities, approximate date of issue, serial number, and form of registration. These requests will be honored only if the identity and right of the requester to the information have been established. Send requests to the addresses shown in (3)(a) or (3)(b) above, depending on the type of security involved.

(a) Requests by a beneficiary for information concerning securities registered in beneficiary form must be accompanied by the name and social security number of the owner and by proof of death of the registered owner.

(b) Requests for records of holdings or other information concerning a deceased or incapacitated individual must be accompanied either by evidence of the requester's appointment as legal representative of the estate of the individual or by a statement attesting that no such representative has been appointed and giving the nature of the relationship between the requester and the individual.

CONTESTING RECORD PROCEDURES:

Initial amendment requests: (1) A request by an individual contesting the content of records or for correction of records must be in writing, signed by the individual involved, identify the system of records, and clearly state that the request is made pursuant to the Privacy Act of 1974. If the request is made in person, identity may be established by the presentation of a single official document bearing the individual's photograph or by the presentation of two items of identification without the photograph but instead showing a name and signature. If the request is made by mail, identity may be established by the presentation of a signature, address, and one other identifier such as a photocopy of an official document bearing the individual's signature. The Bureau of the Public Debt reserves the right to require additional verification of an individual's identity.

(2) Submit requests to the appropriate office as shown under ''System Manager and Address'' above.

(3) The request must specify:

(a) The dates of records in question,

(b) The specific records alleged to be incorrect,

(c) The correction requested, and

(d) The reasons.

(4) The request must include available evidence in support of the request.

Appeals from an initial denial of a request for correction of records: (1) An appeal from an initial denial of a request for correction of records must be in writing, signed by the individual involved, identify the system of records, and clearly state that it is made pursuant to the Privacy Act of 1974. If the individual is making an appeal in person, identity may be established by the presentation of a single official document bearing the individual's photograph or by the presentation of two items of identification without the photograph but showing a name and signature. If the individual is making an appeal by mail, identity may be established by the presentation of a signature, address, and one other identifier such as a photocopy of an official document bearing the individual's signature. The Bureau of the Public Debt reserves the right to require additional verification of an individual's identity.

(2) Appellate determinations will be made by the Commissioner of the Public Debt or the delegate of such officer. Appeals should be addressed to, or delivered personally to: Chief Counsel, Bureau of the Public Debt, 799 9th Street, NW., Room 501, Washington, DC 20239–0001 (or as otherwise provided for in the applicable appendix to 31 CFR part 1, subpart C), within 35 days of the individual's receipt of the initial denial of the requested correction.

(3) An appeal must be marked ''Privacy Act Amendment Appeal'' and specify:

(a) The records to which the appeal relates,

(b) The date of the initial request made for correction of the records, and

(c) The date the initial denial of the request for correction was received.

(4) An appeal must also specify the reasons for the requester's disagreement with the initial denial of correction and must include any applicable supporting evidence.

RECORD SOURCE CATEGORIES:

Information on records in this system is furnished by the individuals or their authorized representatives as listed in ''Categories of Individuals'' and issuing agents for securities or is generated within the system itself.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

TREASURY/BPD.003

SYSTEM NAME:

United States Securities (Other than Savings-Type Securities)-Treasury/BPD.

SYSTEM LOCATION:

Bureau of the Public Debt, Washington, DC, and Parkersburg, WV. Federal Reserve Banks and Branches located at: Atlanta, GA; Baltimore, MD; Birmingham, AL; Boston, MA; Buffalo, NY; Charlotte, NC; Chicago, IL; Cincinnati, OH; Cleveland, OH; Dallas, TX; Denver, CO; Detroit, MI; El Paso, TX; Houston, TX; Jacksonville, FL; Kansas City, MO; Little Rock, AR; Los Angeles, CA; Louisville, KY; Memphis, TN; Miami, FL; Minneapolis, MN; Nashville, TN; New Orleans, LA; New York, NY; Oklahoma City, OK; Omaha, NE; Philadelphia, PA; Pittsburgh, PA; Portland, OR; Richmond, VA; Salt Lake City, UT; San Antonio, TX; San Francisco, CA; Seattle, WA; and St. Louis, MO.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Present and former owners of, subscribers to, claimants to, persons entitled to, and inquirers concerning United States Treasury securities (except savings-type securities) and interest thereon and such securities for which the Treasury acts as agents including, but not limited to, Treasury Bonds, Notes, and Bills; Adjusted Service Bonds; Armed Forces Leave Bonds; and Federal Housing Administration Debentures.

CATEGORIES OF RECORDS IN THE SYSTEM:

(1) Issuance: Records relating to tenders, bids, subscriptions, advices of shipment, requests (applications) for original issue, and correspondence concerning erroneous issue and nonreceipt of securities.

(2) Holdings: Records of ownership and interest activity on registered or recorded United States securities (other than savings-type securities); records about fees for TreasuryDirect accounts exceeding a stipulated amount; change of name and address notices; correspondence concerning errors in registration or recordation; nonreceipt or over- and underpayments of interest and principal; records of interest activity; records of unclaimed accounts; and letters concerning the New York State tax exemption for veterans of World War I.

(3) Transactions (redemptions, payments, reissues, transfers, and exchanges): Records which include securities transaction requests; records about fees for definitive securities issued; legal papers supporting transactions; applications for transfer, disposition, or payment of securities of deceased or incompetent owners; records of Federal estate tax transactions; certificates of ownership covering paid overdue bearer securities; records of erroneous redemption transactions; records of retired securities; and payment records.

(4) Claims: Records including correspondence concerning lost, stolen, destroyed, or mutilated United States securities (other than savings-type securities) or securities for which the Treasury acts as agent and interest coupons thereon; bonds of indemnity; legal documents supporting claims for relief; and records of caveats entered.

(5) Inquiries: Records of correspondence with individuals who have requested information concerning United States Treasury securities (other than savings-type securities) or securities for which the Treasury acts as agent.

(6) All of the above categories of records except ''(4) Claims'' include records of Treasury bills, notes, and bonds in the TreasuryDirect Book-entry Securities System.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 301; 31 U.S.C. 3101 *et seq.*

PURPOSE(S):

Information in this system of records is collected and maintained to enable the Bureau of the Public Debt and its agents to issue United States securities (other than savings-type securities), to process transactions, to make payments, and to identify owners and their accounts.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

These records may be disclosed to:

(1) Agents or contractors of the Department for the purpose of administering the public debt of the United States;

(2) Next-of-kin, voluntary guardian, legal representative or successor in interest of a deceased or incapacitated owner of securities and others entitled upon transfer, exchange, distribution, or payment for the purpose of assuring equitable and lawful disposition of securities and interest;

(3) Any of the owners if the related securities are registered or recorded in the names of two or more owners;

(4) The Internal Revenue Service for the purpose of facilitating the collection of the tax revenues of the United States;

(5) The Department of Justice in connection with lawsuits to which the Department of the Treasury is a party or to trustees in bankruptcy for the purpose of carrying out their duties;

(6) The Veterans Administration when it relates to the holdings of Armed Forces Leave Bonds to facilitate the redemption or disposition of these securities;

(7) Other Federal agencies to effect salary or administrative offset for the purpose of collecting debts;

(8) A consumer reporting agency, including mailing addresses obtained from the Internal Revenue Service, to obtain credit reports;

(9) A debt collection agency, including mailing addresses obtained from the Internal Revenue Service, for debt collection services;

(10) Contractors conducting Treasury-sponsored surveys, polls, or statistical analyses relating to marketing or administration of the public debt of the United States;

(11) Appropriate Federal, State, local, or foreign agencies responsible for investigating or prosecuting the violations of, or for enforcing or implementing, a statute, rule, regulation, order, or license;

(12) A court, magistrate, or administrative tribunal in the course of presenting evidence, including disclosures to opposing counsel or witnesses in the course of civil discovery, litigation, or settlement negotiations or in connection with criminal law proceedings or in response to a subpoena;

(13) A Congressional office in response to an inquiry made at the request of the individual to whom the record pertains;

(14) Disclose through computer matching information on individuals owing debts to the Bureau of the Public Debt to other Federal agencies for the purpose of determining whether the debtor is a Federal employee or retiree receiving payments which may be used to collect the debt through administrative or salary offset;

(15) Disclose through computer matching information on holdings of Treasury securities to requesting Federal agencies under approved agreements limiting the information to that which is relevant in making a determination of eligibility for Federal benefits administered by those agencies; and

(16) Disclose through computer matching, information on individuals with whom the Bureau of the Public Debt has lost contact, to other Federal agencies for the purpose of utilizing letter forwarding services to advise these individuals that they should contact the Bureau about returned payments and/or matured unredeemed securities.

DISCLOSURES TO CONSUMER REPORTING AGENCIES:

Debtor information is also furnished, in accordance with 5 U.S.C. 552a(b)(12) and section 3 of the Debt Collection Act of 1982, to consumer reporting agencies to encourage repayment of an overdue debt.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records in this system are stored on paper, microform, or in electronic media.

RETRIEVABILITY:

Information can be retrieved by social security account number, other assigned identifier, or, in some cases, alphabetically by name or numerically by security serial number. In the case of securities registered in more than one name, information relating thereto can generally only be retrieved by social security number or by the name of the first-named owner.

SAFEGUARDS:

Information is contained in secure buildings, Federal Records Centers, or in areas which are occupied either by officers and responsible employees of the Department who are subject to personnel screening procedures and to the Executive Branch and Treasury Department Standards of Conduct or by agents of the Department who are required by the Department to maintain proper control over records while in their custody. Additionally, since in most cases, numerous steps are involved in the retrieval process, unauthorized persons would be unable to retrieve information in a meaningful form. Information stored in electronic media

is safeguarded by automatic data processing security procedures in addition to physical security measures. Additionally, for those categories of records stored in computers with terminal access, the information cannot be obtained or modified without proper passwords and preauthorized functional capability.

RETENTION AND DISPOSAL:

Records of holdings, forms, documents, and other legal papers which constitute the basis for transactions subsequent to original issue are maintained for such time as is necessary to protect the legal rights and interests of the U.S. Government and the persons affected, or otherwise until they are no longer historically significant. Other records are disposed of at varying intervals in accordance with records retention schedules reviewed and approved by the National Archives and Records Administration (NARA). Paper and microform records ready for disposal are destroyed by shredding or maceration. Records in electronic media are electronically erased using accepted techniques.

SYSTEM MANAGERS AND ADDRESS:

Assistant Commissioner, Securities Operations, Bureau of the Public Debt, Parkersburg, WV 26106–1328.

NOTIFICATION PROCEDURE:

Individuals may submit their requests for determination of whether the system contains records about them or for access to records as provided under ''Records Access Procedures.'' Requests must be made in compliance with the applicable regulations (31 CFR part 1, subpart C). Requests which do not comply fully with these procedures may result in noncompliance with the request, but will be answered to the extent possible.

RECORD ACCESS PROCEDURES:

(1) A request for access to records must be in writing, signed by the individual concerned, identify the system of records, and clearly indicate that the request is made pursuant to the Privacy Act of 1974. If the individual is seeking access in person, identity may be established by the presentation of a single official document bearing the individual's photograph or by the presentation of two items of identification without the photograph but showing a name and signature. If the individual is seeking access by mail, identity may be established by presenting a signature, address, and one other identifier such as a photocopy of an official document bearing the individual's signature. The Bureau of the Public Debt reserves the right to require additional verification of an individual's identity.

(2) The request must state whether the requester wishes to be notified that the record exists or desires to inspect or obtain a copy of the record. If a copy of the record is desired, the requester must agree to pay the fees for copying the documents in accordance with 31 CFR .26(d)(2)(ii).

(3) Requests by individuals about securities they own:

(a) For Treasury bills, notes, or bonds held in the TreasuryDirect Book-entry Securities System: Individuals may contact the nearest TreasuryDirect Office as listed in the Appendix to this system of records, or the Bureau of the Public Debt, Investor Services, Current Income Services Division, Marketable Assistance Branch, Parkersburg, WV 26106–1328. Individuals should provide sufficient information, including their social security number, to identify themselves as owners of securities and sufficient information, including account number, to identify their TreasuryDirect account.

(b) For all other categories of records in this system of records: Individual owners should contact: Bureau of the Public Debt, Investor Services, Current Income Services Division, Marketable Assistance Branch, Parkersburg, WV 26106–1328. Requests must contain information to identify themselves including name, address, and social security number; the type of security involved such as a registered note or bond, an Armed Forces Leave Bond, etc.; and, to the extent possible specify the loan, issue date, denomination, exact form of registration, and other information about the securities.

(4) Requests by individuals who are representatives of owners or their estates require appropriate authority papers. Write to: Bureau of the Public Debt, Investor Services, Current Income Services Division, Marketable Assistance Branch, Parkersburg, WV 26106–1328, to obtain information on these requirements.

(5) In all cases: The request for information will be honored only if the identity and right of the requester to the information have been established.

CONTESTING RECORD PROCEDURES:

Initial amendment requests: (1) A request by an individual contesting the content of records or for correction of records must be in writing, signed by the individual involved, identify the system of records, and clearly state that the request is made pursuant to the Privacy Act of 1974. If the request is made in person, identity may be established by the presentation of a single official document bearing the individual's photograph or by the presentation of two items of identification without the photograph but instead showing a name and signature. If the request is made by mail, identity may be established by the presentation of a signature, address, and one other identifier such as a photocopy of an official document bearing the individual's signature. The Bureau of the Public Debt reserves the right to require additional verification of an individual's identity.

(2) Submit requests to the appropriate office as shown under **SYSTEM MANAGER AND ADDRESS** above.

(3) The request must specify:

(a) The dates of records in question,

(b) The specific records alleged to be incorrect,

(c) The correction requested, and

(d) The reasons.

(4) The request must include available evidence in support of the request.

Appeals from an initial denial of a request for correction of records: (1) An appeal from an initial denial of a request for correction of records must be in writing, signed by the individual involved, identify the system of records, and clearly state that it is made pursuant to the Privacy Act of 1974. If the individual is making an appeal in person, identity may be established by the presentation of a single official document bearing the individual's photograph or by the presentation of two items of identification without the photograph but showing a name and signature. If the individual is making an appeal by mail, identity may be established by the presentation of a signature, address, and one other identifier such as a photocopy of an official document bearing the individual's signature. The Bureau of the Public Debt reserves the right to require additional verification of an individual's identity.

(2) Appellate determinations will be made by the Commissioner of the Public Debt or the delegate of such officer. Appeals should be addressed to, or delivered personally to: Chief Counsel, Bureau of the Public Debt, 799 9th Street, NW., Room 501, Washington, DC 20239–0001 (or as otherwise provided for in the applicable appendix to 31 CFR part 1, subpart C), within 35 days of the individual's receipt of the initial denial of the requested correction.

(3) An appeal must be marked PRIVACY ACT AMENDMENT APPEAL and specify:

(a) The records to which the appeal relates,

(b) The date of the initial request made for correction of the records, and

(c) The date the initial denial of the request for correction was received.

(4) An appeal must also specify the reasons for the requester's disagreement with the initial denial of correction and must include any applicable supporting evidence.

RECORD SOURCE CATEGORIES:

Information contained in records in the system is furnished by the individuals or their authorized representatives as listed in **CATEGORIES OF INDIVIDUALS**, or is generated within the system itself.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

Appendix of TreasuryDirect Contacts

This appendix lists the mailing addresses and telephone numbers of the places that may be contacted by individuals when inquiring about their securities accounts maintained in TreasuryDirect.

TreasuryDirect: P.O. Box 2076, Boston, MA 02106–2076.

TreasuryDirect: P.O. Box 660657, Dallas, TX 75266–0657.

TreasuryDirect: P.O. Box 9150, Minneapolis, MN 55480–9150.

The toll-free telephone number for all three sites is 1–800–722–2678.

TREASURY/BPD.004

SYSTEM NAME:

Controlled Access Security System-Treasury/BPD.

SYSTEM LOCATION:

Bureau of the Public Debt, Parkersburg, WV.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Bureau of the Public Debt employees, employees of contractors and service companies, and official visitors.

CATEGORIES OF RECORDS IN THE SYSTEM:

A record is created for each access to designated areas and contains the individual's name; card number; work shift; access level; time, date, and location of each use of the access card at a card reader.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

31 U.S.C. Sec. 321; 41 CFR 101–20.103.

PURPOSE:

Information in this system of records is collected and maintained to allow the Bureau of the Public Debt to control and verify access to all Parkersburg, West Virginia Public Debt facilities.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

These records may be disclosed to:

(1) Appropriate Federal, State, local, or foreign agencies responsible for investigating or prosecuting the violations of, or for enforcing or implementing a statute, rule, regulation, order, or license;

(2) A Federal, State, or local agency maintaining civil, criminal, or other relevant enforcement information or other pertinent information, which has requested information relevant to or necessary to the requesting agency's or the bureau's hiring or retention of an individual, or issuance of a security clearance, license, contract, grant, or other benefit;

(3) A court, magistrate, or administrative tribunal in the course of presenting evidence, including disclosures to opposing counsel or witnesses in the course of civil discovery, litigation, or settlement negotiations, or in connection with criminal law proceedings, or in response to a subpoena;

(4) A Congressional office in response to an inquiry made at the request of the individual to whom the record pertains;

(5) Unions recognized as exclusive bargaining representatives under the Civil Service Reform Act of 1978, 5 U.S.C. 7111 and 7114, arbitrators and other parties responsible for the administration of the Federal labor-management program if needed in the performance of their authorized duties.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records in this system are stored on paper, microform, or in electronic media.

RETRIEVABILITY:

Information on individuals can be retrieved by name or card number or other assigned identifier.

SAFEGUARDS:

Both the central system and the peripheral system will have limited accessibility. Paper records and magnetic disks are maintained in locked file cabinets with access limited to those personnel whose official duties require access, such as the systems manager, Bureau security officials, and employee relations specialists. Access to terminals is limited through the use of passwords to those personnel whose official duties require access, as for paper records.

RETENTION AND DISPOSAL:

The retention period is for three years. Paper and microform records ready for disposal are destroyed by shredding or maceration. Records in electronic media are electronically erased using accepted techniques.

SYSTEM MANAGERS AND ADDRESS:

Director, Division of Administrative Services, 200 Third Street, Parkersburg, WV 26106–1328.

NOTIFICATION PROCEDURE:

Individuals may submit their requests for determination of whether the system contains records about them or for access to records as provided under ''Records Access Procedures.'' Requests must be made in compliance with the applicable regulations (31 CFR part 1, subpart C). Requests which do not comply fully with these procedures may result in noncompliance with the request, but will be answered to the extent possible.

RECORD ACCESS PROCEDURES:

(1) A request for access to records must be in writing, signed by the individual concerned, identify the system of records, and clearly indicate that the request is made pursuant to the Privacy Act of 1974. If the individual is seeking access in person, identity may be established by the presentation of a single official document bearing the individual's photograph or by the presentation of two items of identification without the photograph but showing a name and signature. If the individual is seeking access by mail, identity may be established by presenting a signature, address, and one other identifier such as a photocopy of an official document bearing the individual's signature. The Bureau of the Public Debt reserves the right to require additional verification of an individual's identity.

(2) Submit requests to the appropriate office as shown under ''System Manager and Address'' above.

(3) The request must state whether the requester wishes to be notified that the record exists or desires to inspect or obtain a copy of the record. If a copy of the record is desired, the requester must agree to pay the fees for copying the documents in accordance with 31 CFR 1.26(d)(2)(ii).

CONTESTING RECORD PROCEDURES:

Initial amendment requests: (1) A request by an individual contesting the content of records or for correction of records must be in writing, signed by the individual involved, identify the system of records, and clearly state that

the request is made pursuant to the Privacy Act of 1974. If the request is made in person, identity may be established by the presentation of a single official document bearing the individual's photograph or by the presentation of two items of identification without the photograph but instead showing a name and signature. If the request is made by mail, identity may be established by the presentation of a signature, address, and one other identifier such as a photocopy of an official document bearing the individual's signature. The Bureau of the Public Debt reserves the right to require additional verification of an individual's identity.

(2) Submit requests to the appropriate office as shown under ''System Manager and Address'' above.

(3) The request must specify:

(a) The dates of records in question,

(b) The specific records alleged to be incorrect,

(c) The correction requested, and

(d) The reasons.

(4) The request must include available evidence in support of the request.

Appeals from an initial denial of a request for correction of records: (1) An appeal from an initial denial of a request for correction of records must be in writing, signed by the individual involved, identify the system of records, and clearly state that it is made pursuant to the Privacy Act of 1974. If the individual is making an appeal in person, identity may be established by the presentation of a single official document bearing the individual's photograph or by the presentation of two items of identification without the photograph but showing a name and signature. If the individual is making an appeal by mail, identity may be established by the presentation of a signature, address, and one other identifier such as a photocopy of an official document bearing the individual's signature. The Bureau of the Public Debt reserves the right to require additional verification of an individual's identity.

(2) Appellate determinations will be made by the Commissioner of the Public Debt or the delegate of such officer. Appeals should be addressed to, or delivered personally to: Chief Counsel, Bureau of the Public Debt, 799 9th Street, NW, Room 501, Washington, DC 20239–0001 (or as otherwise provided for in the applicable appendix to 31 CFR part 1, subpart C), within 35 days of the individual's receipt of the initial denial of the requested correction.

(3) An appeal must be marked ''Privacy Act Amendment Appeal'' and specify:

(a) The records to which the appeal relates,

(b) The date of the initial request made for correction of the records, and

(c) The date the initial denial of the request for correction was received.

(4) An appeal must also specify the reasons for the requester's disagreement with the initial denial of correction and must include any applicable supporting evidence.

RECORD SOURCE CATEGORIES:

The individual concerned, his/her supervisor, or an official of the individual's firm or agency.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

TREASURY/BPD.005

SYSTEM NAME:

Employee Assistance Records-Treasury/BPD.

SYSTEM LOCATION:

Bureau of the Public Debt, 200 Third Street, Parkersburg, WV; and Avery Street Building, 320 Avery Street, Parkersburg, WV. This system covers Public Debt employee assistance records that are maintained by another Federal, State, or local government, or contractor under an agreement with Public Debt directly or through another entity to provide the Employee Assistance Program (EAP) functions. The address of the other agency or contractor may be obtained from the system manager below.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Public Debt employees and former employees who will be or have been counseled, either by self-referral or supervisory-referral regarding drug abuse, alcohol, emotional health, or other personal problems. Where applicable, this system also covers family members of these employees when the family member utilizes the services of the EAP as part of the employee's counseling or treatment process.

CATEGORIES OF RECORDS IN THE SYSTEM:

This system contains records of each employee and, in some cases, family members of the employee who have utilized the Employee Assistance Program for a drug, alcohol, emotional, or personal problem. Examples of information which may be found in each record are the individual's name, social security number, date of birth, grade, job title, home address, telephone numbers, supervisor's name and telephone number, assessment of problem, and referrals to treatment facilities and outcomes.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 301, 7361, 7362, 7904; 44 U.S.C. 3101.

PURPOSE(S):

To provide a history and record of the employee counseling session.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

These records may be disclosed to:

(1) An entity under contract with Public Debt for the purpose of providing the EAP function;

(2) Medical personnel to the extent necessary to meet a bona fide medical emergency in accordance with the Confidentiality of Alcohol and Drug Abuse Patient Records regulations (42 CFR part 2);

(3) Qualified personnel for the purpose of conducting scientific research, management audits, financial audits, or program evaluation, provided individual identifiers are not disclosed in any manner, in accordance with the Confidentiality of Alcohol and Drug Abuse Patient Records regulations (42 CFR part 2);

(4) A third party upon authorization by an appropriate order of a court of competent jurisdiction granted after application showing good cause therefor, in accordance with the Confidentiality of Alcohol and Drug Abuse Patient Records regulations (42 CFR part 2);

(5) The Department of Justice or other appropriate Federal agency in defending claims against the United States when the records are not covered by the Confidentiality of Alcohol and Drug Abuse Patient Records regulations at 42 CFR part 2.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records in this system are stored on paper, microform, or in electronic media.

RETRIEVABILITY:

These records are retrieved by the name and social security number or other assigned identifier of the individual on whom they are maintained.

SAFEGUARDS:

Records are maintained in a secure room in a locked file cabinet, safe, or similar container when not in use. Automated records are protected by restricted access procedures. Access to

records is strictly limited to agency or contractor officials with a bona fide need for the records. When Public Debt contracts with an entity for the purpose of providing the EAP functions, the contractor shall be required to maintain Privacy Act safeguards with respect to such records.

RETENTION AND DISPOSAL:

The retention period is three years after termination of counseling or until any litigation is resolved. Then the records are destroyed.

SYSTEM MANAGER(S) AND ADDRESS:

Director, Human Resources Division, Bureau of the Public Debt, 200 Third Street, Parkersburg, WV 26106–1328.

NOTIFICATION PROCEDURE:

Individuals may submit their requests for determination of whether the system contains records about them or for access to records as provided under ''Records Access Procedures.'' Requests must be made in compliance with the applicable regulations (31 CFR part 1, subpart C). Requests which do not comply fully with these procedures may result in noncompliance with the request, but will be answered to the extent possible.

RECORD ACCESS PROCEDURES:

After you contact the contractor, following are the steps which will be required:

(1) A request for access to records must be in writing, signed by the individual concerned, identify the system of records, and clearly indicate that the request is made pursuant to the Privacy Act of 1974. If the individual is seeking access in person, identity may be established by the presentation of a single official document bearing the individual's photograph or by the presentation of two items of identification without the photograph but showing a name and signature. If the individual is seeking access by mail, identity may be established by presenting a signature, address, and one other identifier such as a photocopy of an official document bearing the individual's signature. The contractor reserves the right to require additional verification of an individual's identity.

(2) Submit requests to the contractor. For information about how to contact the contractor, write to the appropriate office as shown under ''System Manager and Address'' above.

(3) The request must state whether the requester wishes to be notified that the record exists or desires to inspect or obtain a copy of the record. If a copy of the record is desired, the requester must agree to pay the fees for copying the documents in accordance with 31 CFR 1.26(d)(2)(ii).

CONTESTING RECORD PROCEDURES:

Initial amendment requests: After you contact the contractor, following are the steps that will be required:

(1) A request by an individual contesting the content of records or for correction of records must be in writing, signed by the individual involved, identify the system of records, and clearly state that the request is made pursuant to the Privacy Act of 1974. If the request is made in person, identity may be established by the presentation of a single official document bearing the individual's photograph or by the presentation of two items of identification without the photograph but instead showing a name and signature. If the request is made by mail, identity may be established by the presentation of a signature, address, and one other identifier such as a photocopy of an official document bearing the individual's signature. The contractor reserves the right to require additional verification of an individual's identity.

(2) Submit requests to the contractor. For information about how to contact the contractor, write to the appropriate office as shown under ''System Manager and Address'' above.

(3) The request must specify:

(a) The dates of records in question,

(b) The specific records alleged to be incorrect,

(c) The correction requested, and

(d) The reasons.

(4) The request must include available evidence in support of the request.

Appeals from an initial denial of a request for correction of records:

(1) An appeal from an initial denial of a request for correction of records must be in writing, signed by the individual involved, identify the system of records, and clearly state that it is made pursuant to the Privacy Act of 1974. If the individual is making an appeal in person, identity may be established by the presentation of a single official document bearing the individual's photograph or by the presentation of two items of identification without the photograph but showing a name and signature. If the individual is making an appeal by mail, identity may be established by the presentation of a signature, address, and one other identifier such as a photocopy of an official document bearing the individual's signature. The Bureau of the Public Debt reserves the right to require additional verification of an individual's identity.

(2) Appellate determinations will be made by the Commissioner of the Public Debt or the delegate of such officer. Appeals should be addressed to, or delivered personally to: Chief Counsel, Bureau of the Public Debt, 799 9th Street, NW, Room 501, Washington, DC 20239–0001 (or as otherwise provided for in the applicable appendix to 31 CFR part 1, subpart C), within 35 days of the individual's receipt of the initial denial of the requested correction.

(3) An appeal must be marked ''Privacy Act Amendment Appeal'' and specify:

(a) The records to which the appeal relates,

(b) The date of the initial request made for correction of the records, and

(c) The date the initial denial of the request for correction was received.

(4) An appeal must also specify the reasons for the requester's disagreement with the initial denial of correction and must include any applicable supporting evidence.

RECORD SOURCE CATEGORIES:

Information in this system of records comes from the individual to whom it applies, the supervisor of the individual if the individual was referred by a supervisor, or the contractor's staff member who records the counseling session.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

TREASURY/BPD.006

SYSTEM NAME:

Health Service Program Records-Treasury/BPD.

SYSTEM LOCATION:

Bureau of the Public Debt, 200 Third Street, Parkersburg, WV; and Avery Street Building, 320 Avery Street, Parkersburg, WV.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

(1) Bureau of the Public Debt employees who receive services under the Federal Employee Health Services Program from the Public Debt Health Unit in Parkersburg, West Virginia.

(2) Federal employees of other organizations in the Parkersburg, West Virginia vicinity who receive services under the Federal Employee Health Services Program from the Public Debt Health Unit in Parkersburg, West Virginia.

(3) Non-Federal individuals working in or visiting the buildings, who may receive emergency treatment from the Public Debt Health Unit in Parkersburg, West Virginia.

CATEGORIES OF RECORDS IN THE SYSTEM:

This system is comprised of records developed as a result of an individual's utilization of services provided under the Federal Government's Health Service Program. These records contain information such as: Examination, diagnostic, assessment and treatment data; laboratory findings; nutrition and dietetic files; nursing notes; immunization records; blood donor records; CPR training; First Aider; names, social security number, date of birth, handicap code, addresses, and telephone numbers of individual; name, address, and telephone number of individual's physician; name, address, and telephone number of hospital; name, address, and telephone number of emergency contact; and information obtained from the individual's physician; and record of requested accesses by any Public Debt employee (other than Health Unit personnel) who has an official need for the information.

Note: This system does not cover records related to counseling for drug, alcohol, or other problems covered by System No. Treasury/BPD .005-Employee Assistance Records. Medical records relating to a condition of employment or an on-the-job occurrence are covered by the Office of Personnel Management's System of Records No. OPM/GOVT–10-Employee Medical File System Records.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 7901.

PURPOSE(S):

These records document an individual's utilization on a voluntary basis of health services provided under the Federal Government's Health Service Program at the Health Unit at the Bureau of the Public Debt in Parkersburg, West Virginia. Data is necessary to ensure proper evaluation, diagnosis, treatment, and referral to maintain continuity of care; a medical history of care received by the individual; planning for further care of the individual; a means of communication among health care members who contribute to the individual's care; a legal document of health care rendered; a tool for evaluating the quality of health care rendered.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

These records may be disclosed to:

(1) Medical personnel under a contract agreement with Public Debt;

(2) A Federal, State, or local public health service agency as required by applicable law, concerning individuals who have contracted certain communicable diseases or conditions. Such information is used to prevent further outbreak of the disease or condition;

(3) Appropriate Federal, State, or local agencies responsible for investigation of an accident, disease, medical condition, or injury as required by pertinent legal authority;

(4) The Department of Justice in connection with lawsuits in which the Department of the Treasury is a party or has an interest;

(5) A Federal agency responsible for administering benefits programs in connection with a claim for benefits filed by an employee;

(6) A Congressional office from the record of an individual in response to an inquiry from the Congressional office made at the request of that individual;

(7) A court, magistrate, or administrative tribunal in the course of presenting evidence, including disclosures to opposing counsel or witnesses in the course of civil discovery, litigation, or settlement negotiations, or in response to a subpoena or in connection with criminal law proceedings.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records in this system are stored on paper, or in electronic media.

RETRIEVABILITY:

These records are retrieved by the name or other assigned identifier of the individual to whom they pertain.

SAFEGUARDS:

These records are maintained in a secured room with access limited to Health Unit personnel whose duties require access. Medical personnel under a contract agreement who have access to these records are required to maintain adequate safeguards with respect to such records.

RETENTION AND DISPOSAL:

Records are maintained in accordance with National Archives and Records Administration retention schedules. Paper and microform records ready for disposal are destroyed by shredding or maceration. Records in electronic media are electronically erased using accepted techniques.

SYSTEM MANAGER(S) AND ADDRESS:

Director, Division of Administrative Services, Bureau of the Public Debt, Parkersburg, WV 26106–1328.

NOTIFICATION PROCEDURE:

Individuals may submit their requests for determination of whether the system contains records about them or for access to records as provided under ''Records Access Procedures.'' Requests must be made in compliance with the applicable regulations (31 CFR part 1, subpart C). Requests which do not comply fully with these procedures may result in noncompliance with the request, but will be answered to the extent possible.

RECORD ACCESS PROCEDURES:

(1) A request for access to records must be in writing, signed by the individual concerned, identify the system of records, and clearly indicate that the request is made pursuant to the Privacy Act of 1974. If the individual is seeking access in person, identity may be established by the presentation of a single official document bearing the individual's photograph or by the presentation of two items of identification without the photograph but showing a name and signature. If the individual is seeking access by mail, identity may be established by presenting a signature, address, and one other identifier such as a photocopy of an official document bearing the individual's signature. The Bureau of the Public Debt reserves the right to require additional verification of an individual's identity.

(2) Submit requests to the appropriate office as shown under ''System Manager and Address'' above.

(3) The request must state whether the requester wishes to be notified that the record exists or desires to inspect or obtain a copy of the record. If a copy of the record is desired, the requester must agree to pay the fees for copying the documents in accordance with 31 CFR 1.26(d)(2)(ii).

An individual who requests access to a Health Service Program Record shall, at the time the request is made, designate in writing the name of a responsible representative who will be willing to review the record and inform the subject individual of its content. This does not permit the representative to withhold the records from the requester. Rather, the representative is expected to provide access to the records while explaining sensitive or complex information contained in the records.

CONTESTING RECORD PROCEDURES:

Initial amendment requests: (1) A request by an individual contesting the content of records or for correction of records must be in writing, signed by the individual involved, identify the system of records, and clearly state that the request is made pursuant to the Privacy Act of 1974. If the request is

made in person, identity may be established by the presentation of a single official document bearing the individual's photograph or by the presentation of two items of identification without the photograph but instead showing a name and signature. If the request is made by mail, identity may be established by the presentation of a signature, address, and one other identifier such as a photocopy of an official document bearing the individual's signature. The Bureau of the Public Debt reserves the right to require additional verification of an individual's identity.

(2) Submit requests to the appropriate office as shown under ''System Manager and Address'' above.

(3) The request must specify:

(a) The dates of records in question,

(b) The specific records alleged to be incorrect,

(c) The correction requested, and

(d) The reasons.

(4) The request must include available evidence in support of the request.

Appeals from an initial denial of a request for correction of records: (1) An appeal from an initial denial of a request for correction of records must be in writing, signed by the individual involved, identify the system of records, and clearly state that it is made pursuant to the Privacy Act of 1974. If the individual is making an appeal in person, identity may be established by the presentation of a single official document bearing the individual's photograph or by the presentation of two items of identification without the photograph but showing a name and signature. If the individual is making an appeal by mail, identity may be established by the presentation of a signature, address, and one other identifier such as a photocopy of an official document bearing the individual's signature. The Bureau of the Public Debt reserves the right to require additional verification of an individual's identity.

(2) Appellate determinations will be made by the Commissioner of the Public Debt or the delegate of such officer. Appeals should be addressed to, or delivered personally to: Chief Counsel, Bureau of the Public Debt, 799 9th Street, NW, Room 501, Washington, DC 20239–0001 (or as otherwise provided for in the applicable appendix to 31 CFR part 1, subpart C), within 35 days of the individual's receipt of the initial denial of the requested correction.

(3) An appeal must be marked ''Privacy Act Amendment Appeal'' and specify:

(a) The records to which the appeal relates,

(b) The date of the initial request made for correction of the records, and

(c) The date the initial denial of the request for correction was received.

(4) An appeal must also specify the reasons for the requester's disagreement with the initial denial of correction and must include any applicable supporting evidence.

RECORD SOURCE CATEGORIES:

Information in this system of records comes from the individual to whom it applies; laboratory reports and test results; Health Unit physicians, nurses, and other medical technicians who have examined, tested, or treated the individual; the individual's personal physician; other Federal employee health units; and other Federal agencies.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

TREASURY/BPD.007

SYSTEM NAME:

Gifts to Reduce the Public Debt-Treasury/BPD.

SYSTEM LOCATION:

Bureau of the Public Debt, 200 Third Street, Parkersburg, WV.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Donors of gifts to reduce the public debt.

CATEGORIES OF RECORDS IN THE SYSTEM:

Correspondence; copies of checks, money orders, or other payments; copies of wills and other legal documents; and other material related to gifts to reduce the public debt, received on or after October 1, 1984, by the Bureau of the Public Debt either directly from the donor or through the donor's Congressional or other representative.

Note: This system does not cover gifts to reduce the public debt received prior to October 1, 1984, when this function was handled by the Financial Management Service. This system of records does not cover gifts sent to other agencies, such as gifts sent with one's Federal income tax return to the Internal Revenue Service. This system does not include any other gifts to the United States.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

31 U.S.C. 3113.

PURPOSES:

These records document the receipt from donors of gifts to reduce the public debt. They provide a record of correspondence acknowledging receipt, information concerning any legal matters, and a record of depositing the gift and accounting for it.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

These records may be used to:

(1) Disclose pertinent information to appropriate Federal, State, local, or foreign agencies responsible for investigating or prosecuting the violations of, or for enforcing or implementing a statute, rule, regulation, order, or license;

(2) Disclose information to a court, magistrate, or administrative tribunal in the course of presenting evidence including disclosures to opposing counsel or witnesses in the course of civil discovery, litigation, or settlement negotiations, or in response to a subpoena, or in connection with criminal law proceedings;

(3) Provide information to a Congressional office in response to an inquiry made at the request of the individual to whom the record pertains;

(4) Disclose information to agents or contractors of the Department for the purpose of administering the public debt of the United States;

(5) Disclose information to a legal representative of a deceased donor for the purpose of properly administering the estate of the deceased;

(6) Disclose information to the Internal Revenue Service for the purpose of confirming whether a tax-deductible event has occurred;

(7) Disclose information to the Department of Justice in connection with lawsuits in which the Department of the Treasury is a party or has an interest.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records in this system are stored on paper, microform, or in electronic media.

RETRIEVABILITY:

These records are retrieved by the name of the donor; amount of gift; type of gift; date of gift; social security number of donor, if provided; control number; check number; State code; or other assigned identifier.

SAFEGUARDS:

These records are maintained in controlled access areas. Automated records are protected by restricted access procedures. Checks and other payments are stored in locked safes with access limited to personnel whose duties require access.

RETENTION AND DISPOSAL:

Records of gifts to reduce the public debt are maintained in accordance with

National Archives and Records Administration retention schedules. Paper and microform records ready for disposal are destroyed by shredding or maceration. Records in electronic media are electronically erased using accepted techniques.

SYSTEM MANAGERS AND ADDRESS:

Branch Manager, Current Income and Transactions Accounting Branch, Division of Accounting Services, Securities Operations, Bureau of the Public Debt, Parkersburg, WV 26101.

NOTIFICATION PROCEDURE:

Individuals may submit their requests for determination of whether the system contains records about them or for access to records as provided under ''Records Access Procedures.'' Requests must be made in compliance with the applicable regulations (31 CFR part 1, subpart C). Requests which do not comply fully with these procedures may result in noncompliance with the request, but will be answered to the extent possible.

RECORD ACCESS PROCEDURES:

(1) A request for access to records must be in writing, signed by the individual concerned, identify the system of records, and clearly indicate that the request is made pursuant to the Privacy Act of 1974. If the individual is seeking access in person, identity may be established by the presentation of a single official document bearing the individual's photograph or by the presentation of two items of identification without the photograph but showing a name and signature. If the individual is seeking access by mail, identity may be established by presenting a signature, address, and one other identifier such as a photocopy of an official document bearing the individual's signature. The Bureau of the Public Debt reserves the right to require additional verification of an individual's identity.

(2) Submit requests to the appropriate office as shown under ''System Manager and Address'' above.

(3) The request must state whether the requester wishes to be notified that the record exists or desires to inspect or obtain a copy of the record. If a copy of the record is desired, the requester must agree to pay the fees for copying the documents in accordance with 31 CFR 1.26(d)(2)(ii).

CONTESTING RECORD PROCEDURES:

Initial amendment requests: (1) A request by an individual contesting the content of records or for correction of records must be in writing, signed by the individual involved, identify the system of records, and clearly state that the request is made pursuant to the Privacy Act of 1974. If the request is made in person, identity may be established by the presentation of a single official document bearing the individual's photograph or by the presentation of two items of identification without the photograph but instead showing a name and signature. If the request is made by mail, identity may be established by the presentation of a signature, address, and one other identifier such as a photocopy of an official document bearing the individual's signature. The Bureau of the Public Debt reserves the right to require additional verification of an individual's identity.

(2) Submit requests to the appropriate office as shown under ''System Manager and Address'' above.

(3) The request must specify:

(a) The dates of records in question,

(b) The specific records alleged to be incorrect,

(c) The correction requested, and

(d) The reasons.

(4) The request must include available evidence in support of the request.

Appeals from an initial denial of a request for correction of records: (1) An appeal from an initial denial of a request for correction of records must be in writing, signed by the individual involved, identify the system of records, and clearly state that it is made pursuant to the Privacy Act of 1974. If the individual is making an appeal in person, identity may be established by the presentation of a single official document bearing the individual's photograph or by the presentation of two items of identification without the photograph but showing a name and signature. If the individual is making an appeal by mail, identity may be established by the presentation of a signature, address, and one other identifier such as a photocopy of an official document bearing the individual's signature. The Bureau of the Public Debt reserves the right to require additional verification of an individual's identity.

(2) Appellate determinations will be made by the Commissioner of the Public Debt or the delegate of such officer. Appeals should be addressed to, or delivered personally to: Chief Counsel, Bureau of the Public Debt, 799 9th Street, NW, Room 501, Washington, DC 20239–0001 (or as otherwise provided for in the applicable appendix to 31 CFR part 1, subpart C), within 35 days of the individual's receipt of the initial denial of the requested correction.

(3) An appeal must be marked ''Privacy Act Amendment Appeal'' and specify:

(a) The records to which the appeal relates,

(b) The date of the initial request made for correction of the records, and

(c) The date the initial denial of the request for correction was received.

(4) An appeal must also specify the reasons for the requester's disagreement with the initial denial of correction and must include any applicable supporting evidence.

RECORD SOURCE CATEGORIES:

Information in this system of records comes from the individual to whom it applies, executors, administrators, and other involved persons.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

TREASURY/BPD.008

SYSTEM NAME:

Retail Treasury Securities Access Application-Treasury/BPD.

SYSTEM LOCATION:

Records are maintained at the following Public Debt locations:

(1) 200 Third Street, Parkersburg, WV;

(2) Park Center, 90 Park Center, Parkersburg, WV;

(3) H.J. Hintgen Building, 2nd and Avery Streets, Parkersburg, WV;

(4) United Building, 5th and Avery Streets, Parkersburg, WV;

(5) Avery Street Building, 320 Avery Street, Parkersburg, WV., and

(6) 799 9th Street, NW., Washington, DC.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Records cover those individuals who own or make inquiries concerning United States Treasury securities.

CATEGORIES OF RECORDS IN THE SYSTEM:

The types of personal information collected/used by this system are necessary to ensure the accurate identification of individuals doing business with Public Debt or to provide personalized service to these individuals. The types of personal information presently include or potentially could include the following:

(a) Personal identifiers (name, including previous name used; social security number; physical and electronic addresses; telephone, fax, and pager numbers);

(b) Authentication aids (personal identification number, password, account number, shared-secret identifier, digitized signature, or other unique identifier);

(c) Customer demographics (age, gender, marital status, income, number in household, etc.); and

(d) Customer preferences (favorite color, hobby, magazine, etc.; preferred sources for information, such as television, newspaper, Internet, etc.; or dates of importance to the customer, such as birth, anniversary, etc.).

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 301; 31 U.S.C. 3101, et seq.

PURPOSE(S):

The purpose of this system of records is to support Public Debt business processes, process electronic services to the public (E-government), and improve service to investors in Treasury securities.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

These records may be disclosed to:

(1) Appropriate Federal, State, local, or foreign agencies or other public authority responsible for investigating or prosecuting the violations of, or for enforcing or implementing a statute, rule, regulation, order or license where the disclosing agency becomes aware of an indication of a violation or potential violation of civil or criminal law or regulation;

(2) A court, magistrate, or administrative tribunal in the course of presenting evidence, including disclosures to opposing counsel or witnesses in the course of civil discovery, litigation, or settlement negotiations, or in response to a court-ordered subpoena, or in connection with criminal law proceedings where relevant or potentially relevant to a proceeding;

(3) A Congressional office in response to an inquiry made at the request of the individual to whom the record pertains;

(4) Agents or contractors who have been engaged to assist the Bureau of the Public Debt in the performance of a service related to this system of records and who need to have access to the records in order to perform the activity;

(5) The Department of Justice when seeking legal advice or when

(a) The Department of the Treasury (agency) or

(b) The Bureau of the Public Debt, or

(c) Any employee of the agency in his or her official capacity, or

(d) Any employee of the agency in his or her individual capacity where the Department of Justice has agreed to represent the employee, or

(e) The United States, where the agency determines that litigation is likely to affect the agency or the Bureau of the Public Debt, is a party to litigation or has an interest in such litigation, and the use of such records by the Department of Justice is deemed by the agency to be relevant and necessary to the litigation.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are maintained on electronic media, multiple client-server platforms that are backed up to magnetic tape, microform, or other storage media, and/or hard copy.

RETRIEVABILITY:

Records may be retrieved by name, alias names, social security number, account number, or other unique identifier.

SAFEGUARDS:

Public Debt has sophisticated Internet firewall security via hardware and software configurations as well as specific monitoring tools. Records are maintained in controlled access areas. Identification cards are verified to ensure that only authorized personnel are present. Electronic records are protected by restricted access procedures, including the use of passwords, sign-on protocols, and user authentication that are periodically changed. Only employees whose official duties require access are allowed to view, administer, and control these records.

RETENTION AND DISPOSAL:

Public Debt is in the process of requesting approval of a new records schedule that will permit records to be maintained for not more than 90 calendar days after the business relationship with the customer ends. These records will not be destroyed until we receive such approval. Paper and microform records ready for disposal are destroyed by shredding or maceration. Records in electronic media are electronically erased using accepted techniques.

SYSTEM MANAGER(S) AND ADDRESS:

Assistant Commissioner and Chief Information Officer, Office of Information Technology, Bureau of the Public Debt, 200 Third Street, Parkersburg, WV 26101.

NOTIFICATION PROCEDURE:

Individuals may submit their requests for determination of whether the system contains records about them or for access to records as provided under ''Records Access Procedures.'' Requests must be made in compliance with the applicable regulations (31 CFR part 1, subpart C). Requests which do not comply fully with these procedures may result in noncompliance with the request, but will be answered to the extent possible.

RECORD ACCESS PROCEDURES:

(1) A request for access to records must be in writing, signed by the individual concerned, identify the system of records, and clearly indicate that the request is made pursuant to the Privacy Act of 1974. If the individual is seeking access in person, identity may be established by the presentation of a single official document bearing the individual's photograph or by the presentation of two items of identification without the photograph but showing a name and signature. If the individual is seeking access by mail, identity may be established by presenting a signature, address, and one other identifier such as a photocopy of an official document bearing the individual's signature. The Bureau of the Public Debt reserves the right to require additional verification of an individual's identity.

(2) Submit requests to the appropriate office as shown under ''System Manager and Address'' above.

(3) The request must state whether the requester wishes to be notified that the record exists or desires to inspect or obtain a copy of the record. If a copy of the record is desired, the requester must agree to pay the fees for copying the documents in accordance with 31 CFR 1.26(d)(2)(ii).

CONTESTING RECORD PROCEDURES:

Initial amendment requests: (1) A request by an individual contesting the content of records or for correction of records must be in writing, signed by the individual involved, identify the system of records, and clearly state that the request is made pursuant to the Privacy Act of 1974. If the request is made in person, identity may be established by the presentation of a single official document bearing the individual's photograph or by the presentation of two items of identification without the photograph but instead showing a name and signature. If the request is made by mail, identity may be established by the presentation of a signature, address, and one other identifier such as a photocopy of an official document bearing the individual's signature. The Bureau of the Public Debt reserves the right to require additional verification of an individual's identity.

(2) Submit requests to the appropriate office as shown under ''System Manager and Address'' above.

(3) The request must specify:

(a) The dates of records in question,

(b) The specific records alleged to be incorrect,

(c) The correction requested, and

(d) The reasons.

(4) The request must include available evidence in support of the request.

Appeals from an initial denial of a request for correction of records: (1) An appeal from an initial denial of a request for correction of records must be in writing, signed by the individual involved, identify the system of records, and clearly state that it is made pursuant to the Privacy Act of 1974. If the individual is making an appeal in person, identity may be established by the presentation of a single official document bearing the individual's photograph or by the presentation of two items of identification without the photograph but showing a name and signature. If the individual is making an appeal by mail, identity may be established by the presentation of a signature, address, and one other identifier such as a photocopy of an official document bearing the individual's signature. The Bureau of the Public Debt reserves the right to require additional verification of an individual's identity.

(2) Appellate determinations will be made by the Commissioner of the Public Debt or the delegate of such officer. Appeals should be addressed to, or delivered personally to: Chief Counsel, Bureau of the Public Debt, 799 9th Street, NW., Room 501, Washington, DC 20239–0001 (or as otherwise provided for in the applicable appendix to 31 CFR part 1, subpart C), within 35 days of the individual's receipt of the initial denial of the requested correction.

(3) An appeal must be marked ''Privacy Act Amendment Appeal'' and specify:

(a) The records to which the appeal relates,

(b) The date of the initial request made for correction of the records, and

(c) The date the initial denial of the request for correction was received.

(4) An appeal must also specify the reasons for the requester's disagreement with the initial denial of correction and must include any applicable supporting evidence.

RECORD SOURCE CATEGORIES:

Information is provided by the individual covered by this system of records or, with their authorization, is derived from other systems of records.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

TREASURY/BPD.009

SYSTEM NAME:

U.S. Treasury Securities Fraud Information System—Treasury/BPD.

SYSTEM LOCATION:

The system of records is located at the Bureau of the Public Debt in Parkersburg, WV and Washington DC as well as the Federal Reserve Banks of Boston, Buffalo, Chicago, Dallas, Kansas City, Philadelphia, Pittsburgh, Richmond, and Minneapolis. This system also covers Public Debt records that are maintained by contractor(s) under agreement. The system manager(s) maintain(s) the system location of these records. The address(es) of the contractor(s) may be obtained from the system manager(s) below.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals under investigation or who make inquiries or report fraudulent or suspicious activities related to Treasury securities and other U.S. obligations.

CATEGORIES OF RECORDS IN THE SYSTEM:

The types of personal information collected/used by this system are necessary to ensure the accurate identification of individuals who report or make fraudulent transactions involving Treasury securities and other U.S. obligations. The types of personal information potentially could include the following:

(1) Personal identifiers (name, including previous name used, and aliases; Social Security number; Tax Identification Number; physical and electronic addresses; telephone, fax, and pager numbers), and;

(2) Authentication aids (personal identification number, password, account number, credit card number, shared-secret identifier, digitized signature, or other unique identifier).

Supporting records may contain correspondence between Public Debt and the entity or individual submitting a complaint or inquiry, correspondence between Public Debt and the Department of Treasury, or correspondence between Public Debt and law enforcement, regulatory bodies, or other third parties.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

31 U.S.C. 321(a)(5), 31 U.S.C. 333, 31 U.S.C. 3101, *et seq.* 31 U.S.C. 5318, and 5 U.S.C. 301.

PURPOSE(S):

Records in this system are used to: (1) Identify and monitor fraudulent and suspicious activity related to Treasury securities and other U.S. obligations; (2) ensure that Public Debt provides a timely and appropriate notification of a possible violation of law to law enforcement and regulatory agencies; (3) protect the Government and individuals from fraud and loss; (4) prevent the misuse of Treasury names and symbols on fraudulent instruments; and, (5) compile summary reports, that conform with the spirit of the USA Patriot Act's anti-terrorism financing provisions and the Bank Secrecy Act's anti-money laundering provisions, and submit the reports to the Financial Crimes Enforcement Network (FinCEN).

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

These records may be disclosed to:

(1) Congressional offices in response to an inquiry made at the request of the individual to whom the record pertains;

(2) Appropriate Federal, State, local, or foreign agencies responsible for investigating or prosecuting the violations of, or for enforcing or implementing a statute, rule, regulation, order, or license, where the disclosing agency becomes aware of a potential violation of civil or criminal law or regulation;

(3) A court, magistrate, or administrative tribunal in the course of presenting evidence, including disclosures to opposing counsel or witnesses in the course of civil discovery, litigation, or settlement negotiations or in connection with criminal law proceedings or in response to a subpoena;

(4) Third parties during the course of an investigation to the extent necessary to obtain information pertinent to the investigation;

(5) Agents or contractors who have been engaged to assist Public Debt in the performance of a service related to this system of records and who need to have access to the records in order to perform the activity;

(6) The Department of Justice when seeking legal advice or when (a) the Department of the Treasury or (b) Public Debt, or (c) any employee of the agency in his or her official capacity, or (d) any employee of the agency in his or her individual capacity where the Department of Justice has agreed to represent the employee, or (e) the United States, where the agency determines that litigation is likely to affect the agency, is a party to litigation or has an interest in such litigation, and

the use of such records by the Department of Justice is deemed by the agency to be relevant and necessary to the litigation.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are maintained on electronic media, multiple client-server platforms that are backed-up to magnetic tape or other storage media, and/or hard copy.

RETRIEVABILITY:

Records may be retrieved by (name, alias name, Social Security number, Tax Identification Number, account number, or other unique identifier).

SAFEGUARDS:

These records are maintained in controlled access areas. Identification cards are verified to ensure that only authorized personnel are present. Electronic records are protected by restricted access procedures, including the use of passwords and sign-on protocols which are periodically changed. Only employees whose official duties require access are allowed to view, administer, and control these records. Copies of records maintained on computer have the same limited access as paper records.

RETENTION AND DISPOSAL:

Records are maintained in accordance with National Archives and Records Administration retention schedules. Paper and microform records ready for disposal are destroyed by shredding or maceration. Records in electronic media are electronically erased using accepted techniques.

SYSTEM MANAGER(S) AND ADDRESS:

(1) Assistant Commissioner, Office of Information Technology, Bureau of the Public Debt, 200 Third Street, Parkersburg, WV 26101

(2) Assistant Commissioner, Office of Investor Services, Bureau of the Public Debt, 200 Third Street, Parkersburg, WV 26101

(3) Assistant Commissioner, Office of Securities Operations, Bureau of the Public Debt, 200 Third Street, Parkersburg, WV 26101

(4) Chief Counsel, Office of Chief Counsel, Parkersburg Division, Bureau of the Public Debt, 200 Third Street, Parkersburg, WV 26101

NOTIFICATION PROCEDURE:

This system of records is exempt from the Privacy Act provision on notification procedures. (See ''Exemptions Claimed for the System,'' below.) An individual wishing to be notified if he or she is named in non-exempt records maintained in this system must submit a written request to the Disclosure Officer. See 31 CFR part 1, Subpart C, appendix I.

Identification Requirements: An individual seeking notification through the mail must establish his or her identity by providing a signature and an address as well as one other identifier bearing the individual's name and signature (such as a photocopy of a driver's license or other official document). An individual seeking notification in person must establish his or her identity by providing proof in the form of a single official document bearing a photograph (such as a passport or identification badge) or two items of identification that bear both a name and signature.

Alternatively, identity may be established by providing a notarized statement, swearing or affirming to an individual's identity, and to the fact that the individual understands the penalties provided in 5 U.S.C. 552a(i)(3) for requesting or obtaining information under false pretenses. Additional documentation establishing identity or qualification for notification may be required, such as in an instance where a legal guardian or representative seeks notification on behalf of another individual.

RECORD ACCESS PROCEDURES:

This system of records is exempt from the Privacy Act provision on record access procedures. (See ''Notification Procedure'' above.)

CONTESTING RECORD PROCEDURES:

This system of records is exempt from the Privacy Act provision on contesting record procedures. (See ''Notification Procedure'' above.)

RECORD SOURCE CATEGORIES:

This system of records is exempt from the Privacy Act provision which requires that record source categories be reported. (See ''Exemptions Claimed for the System,'' below.)

EXEMPTIONS CLAIMED FOR THE SYSTEM:

Records maintained in this system have been designated as exempt from 5 U.S.C. 552a(c)(3), (d)(1), (2), (3), and (4), (e)(1), (e)(4)(G), (H), and (I), and (f) of the Privacy Act pursuant to 5 U.S.C. 552a(k)(2). See 31 CFR 1.36.

[FR Doc. 05–11503 Filed 6–9–05; 8:45 am]

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Federal Register

Friday,
June 10, 2005

Part II

Department of the Treasury

Office of the Comptroller of the Currency

12 CFR Part 41

Office of Thrift Supervision

12 CFR Part 571

Federal Reserve System

12 CFR Parts 222 and 232

Federal Deposit Insurance Corporation

12 CFR Part 334

National Credit Union Administration

12 CFR Part 717

Fair Credit Reporting Medical Information Regulations; Interim Final Rule

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

12 CFR Part 41

[Docket No. 05–10]

RIN 1557–AC85

FEDERAL RESERVE SYSTEM

12 CFR Parts 222 and 232

[Regulation V and FF; Docket No. R–1188]

FEDERAL DEPOSIT INSURANCE CORPORATION

12 CFR Part 334

RIN 3064–AC81

DEPARTMENT OF THE TREASURY

Office of Thrift Supervision

12 CFR Part 571

[No. 2005–16]

RIN 1550–AB88

NATIONAL CREDIT UNION ADMINISTRATION

12 CFR Part 717

Fair Credit Reporting Medical Information Regulations

AGENCIES: Office of the Comptroller of the Currency, Treasury (OCC); Board of Governors of the Federal Reserve System (Board); Federal Deposit Insurance Corporation (FDIC); Office of Thrift Supervision, Treasury (OTS); National Credit Union Administration (NCUA).

ACTION: Interim final rules; request for public comments.

SUMMARY: The OCC, Board, FDIC, OTS, and NCUA (Agencies) are publishing interim final rules to implement section 411 of the Fair and Accurate Credit Transactions Act of 2003 (FACT Act). The interim final rules create exceptions to the statute's general prohibition on creditors obtaining or using medical information pertaining to a consumer in connection with any determination of the consumer's eligibility, or continued eligibility, for credit for all creditors. The exceptions permit creditors to obtain or use medical information in connection with credit eligibility determinations where necessary and appropriate for legitimate purposes, consistent with the Congressional intent to restrict the use of medical information for inappropriate purposes. The interim final rules also create limited exceptions to permit affiliates to share medical information with each other without becoming consumer reporting agencies.

DATES: This interim final rule is effective March 7, 2006. Comments must be received by July 11, 2005.

ADDRESSES: Comments should be directed to:

OCC: You should include OCC and Docket Number 05–10 in your comment. You may submit comments by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *OCC Web Site: http://www.occ.treas.gov.* Click on ''Contact the OCC,'' scroll down and click on ''Comments on proposed regulations.''
- *E-mail Address: regs.comments@occ.treas.gov.*
- *Fax:* (202) 874–4448.
- *Mail:* Office of the Comptroller of the Currency, 250 E Street, SW., Mail Stop 1–5, Washington, DC 20219.
- *Hand Delivery/Courier:* 250 E Street, SW., Attn: Public Information Room, Mail Stop 1–5, Washington, DC 20219.

Instructions: All submissions received must include the agency name (OCC) and docket number or Regulatory Information Number (RIN) for this rulemaking. In general, OCC will enter all comments received into the docket without change, including any business or personal information that you provide. You may review comments and other related materials by any of the following methods:

- *Viewing Comments Personally:* You may personally inspect and photocopy comments at the OCC's Public Information Room, 250 E Street, SW., Washington, DC. You can make an appointment to inspect comments by calling (202) 874–5043.
- *Viewing Comments Electronically:* You may request e-mail or CD–ROM copies of comments that the OCC has received by contacting the OCC's Public Information Room at *regs.comments@occ.treas.gov.*
- *Docket:* You may also request available background documents and project summaries using the methods described above.

Board: You may submit comments, identified by Docket No. R–1188, by any of the following methods:

- *Agency Web Site: http://www.federalreserve.gov.* Follow the instructions for submitting comments at *http://www.federalreserve.gov/generalinfo/foia/ProposedRegs.cfm.*
- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *E-mail: regs.comments@federalreserve.gov.* Include docket number in the subject line of the message.
- *Fax:* 202/452–3819 or 202/452–3102.
- *Mail:* Jennifer J. Johnson, Secretary, Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue, NW., Washington, DC 20551.

All public comments are available from the Board's Web site at *http://www.federalreserve.gov/generalinfo/foia/ProposedRegs.cfm* as submitted, except as necessary for technical reasons. Accordingly, your comments will not be edited to remove any identifying or contact information. Public comments may also be viewed electronically or in paper in Room MP–500 of the Board's Martin Building (20th and C Streets, NW.) between 9 a.m. and 5 p.m. on weekdays.

FDIC: You may submit comments, identified by RIN number by any of the following methods:

- *Agency Web Site: http://www.fdic.gov/regulations/laws/federal/propose.html.* Follow instructions for submitting comments on the Agency Web Site.
- *E-Mail: Comments@FDIC.gov.* Include the RIN number in the subject line of the message.
- *Mail:* Robert E. Feldman, Executive Secretary, Attention: Comments, Federal Deposit Insurance Corporation, 550 17th Street, NW., Washington, DC 20429.
- *Hand Delivery/Courier:* Guard station at the rear of the 550 17th Street Building (located on F Street) on business days between 7 a.m. and 5 p.m.
- *Instructions:* All submissions received must include the agency name and RIN for this rulemaking. All comments received will be posted without change to *http://www.fdic.gov/regulations/laws/federal/propose.html* including any personal information provided.

OTS: You may submit comments, identified by number 2005–16, by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *E-mail Address: regs.comments@ots.treas.gov.* Please include number 2005–16 in the subject line of the message and include your name and telephone number in the message.
- *Fax:* (202) 906–6518.
- *Mail:* Regulation Comments, Chief Counsel's Office, Office of Thrift

Supervision, 1700 G Street, NW., Washington, DC 20552, Attention: No. 2005–16.

• *Hand Delivery/Courier:* Guard's Desk, East Lobby Entrance, 1700 G Street, NW., from 9 a.m. to 4 p.m. on business days, Attention: Regulation Comments, Chief Counsel's Office, Attention: No. 2005–16.

Instructions: All submissions received must include the agency name and docket number or Regulatory Information Number (RIN) for this rulemaking. All comments received will be posted without change to the OTS Internet Site at *http://www.ots.treas.gov/pagehtml.cfm?catNumber=67&an=1,* including any personal information provided.

Docket: For access to the docket to read background documents or comments received, go to *http://www.ots.treas.gov/pagehtml.cfm?catNumber=67&an=1.* In addition, you may inspect comments at the Public Reading Room, 1700 G Street, NW., by appointment. To make an appointment for access, call (202) 906–5922, send an e-mail to *public.info@ots.treas.gov,* or send a facsimile transmission to (202) 906–7755. (Prior notice identifying the materials you will be requesting will assist us in serving you.) We schedule appointments on business days between 10 a.m. and 4 p.m. In most cases, appointments will be available the next business day following the date we receive a request.

NCUA: You may submit comments by any of the following methods (Please send comments by one method only):

• *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

• *NCUA Web Site: http://www.ncua.gov/RegulationsOpinionsLaws/proposed_regs/proposed_regs.html.* Follow the instructions for submitting comments.

• *E-mail:* Address to *regcomments@ncua.gov.* Include ''[Your name] Comments on Interim Final Rule Part 717, Fair Credit Reporting—Medical Information'' in the e-mail subject line.

• *Fax:* (703) 518–6319. Use the subject line described above for e-mail.

• *Mail:* Address to Mary Rupp, Secretary of the Board, National Credit Union Administration, 1775 Duke Street, Alexandria, Virginia 22314–3428.

• *Hand Delivery/Courier:* Address to Mary Rupp, Secretary of the Board, National Credit Union Administration. Deliver to guard station in the lobby of 1775 Duke Street, Alexandria, Virginia 22314–3428, on business days between 8 a.m. and 5 p.m.

All public comments are available on the agency's Web site at *http://www.ncua.gov/RegulationsOpinionsLaws/comments* as submitted, except as may not be possible for technical reasons. Public comments will not be edited to remove any identifying or contact information. Paper copies of comments may be inspected in NCUA's law library, at 1775 Duke Street, Alexandria, Virginia 22314, by appointment weekdays between 9 a.m. and 3 p.m. To make an appointment, call (703) 518–6546 or send an e-mail to *OGCMail@ncua.gov.*

FOR FURTHER INFORMATION CONTACT:

OCC: Amy Friend, Assistant Chief Counsel, (202) 874–5200; Michael Bylsma, Director, or Stephen Van Meter, Assistant Director, Community and Consumer Law, (202) 874–5750; Patrick T. Tierney, Senior Attorney, Legislative and Regulatory Activities Division, (202) 874–5090; or Carol Turner, Compliance Specialist, Compliance Department, (202) 874–4858, Office of the Comptroller of the Currency, 250 E Street, SW., Washington, DC 20219.

Board: David A. Stein, Counsel; Minh-Duc T. Le, Ky Tran-Trong, or Krista P. DeLargy, Senior Attorneys, Division of Consumer and Community Affairs, (202) 452–3667 or (202) 452–2412; or Andrew Miller, Counsel, Legal Division, (202) 452–3428, Board of Governors of the Federal Reserve System, 20th and C Streets, NW., Washington, DC 20551.

FDIC: Richard M. Schwartz, Counsel, Legal Division, (202) 898–7424; David Lafleur, Policy Analyst, (202) 898–6569, or Patricia Cashman, Senior Policy Analyst, Division of Supervision and Consumer Protection, (202) 898–6534, Federal Deposit Insurance Corporation, 550 17th Street, NW., Washington, DC 20429.

OTS: Elizabeth Baltierra, Program Analyst (Compliance), Compliance Policy, (202) 906–6540; Richard Bennett, Counsel, (202) 906–7409; Judith A. McCormick, Director, Consumer Protection and Specialty Programs, (202) 906–5636, Office of Thrift Supervision, 1700 G Street, NW., Washington, DC 20552.

NCUA: Regina M. Metz, Staff Attorney, Office of General Counsel, (703) 518–6540, National Credit Union Administration, 1775 Duke Street, Alexandria, VA 22314–3428.

SUPPLEMENTARY INFORMATION:

I. Background

The FACT Act became law on December 4, 2003. Pub. L. 108–159, 117 Stat. 1952. In general, the FACT Act amends the Fair Credit Reporting Act (FCRA or Act) to enhance the ability of consumers to combat identity theft, increase the accuracy of consumer reports, and allow consumers to exercise greater control regarding the type and amount of marketing solicitations they receive. Section 411 of the FACT Act generally limits the ability of creditors to obtain or use medical information in connection with credit eligibility determinations, consumer reporting agencies to disclose medical information, and all persons to share medical information and other medical-related information with affiliates.

Section 411(a) of the FACT Act adds a new section 604(g)(1) to the FCRA to restrict the circumstances under which consumer reporting agencies may furnish consumer reports that contain medical information about consumers. Under section 604(g)(1), a consumer reporting agency may not furnish a consumer report that contains medical information about a consumer unless:

(1) The report is furnished in connection with an insurance transaction, and the consumer affirmatively consents to the furnishing of the report;

(2) The report is furnished for employment purposes or in connection with a credit transaction, the information to be furnished is relevant to process or effect the employment or credit transaction, and the consumer provides specific written consent for the furnishing of the report that describes in clear and conspicuous language the use for which the information will be furnished; or

(3) The information to be furnished pertains solely to transactions, accounts, or balances relating to debts arising from the receipt of medical services, products, or devices, where such information, other than account status or amounts, is restricted or reported using codes that do not identify, or do not provide information sufficient to infer, the specific provider or the nature of such services, products, or devices.

Section 411(c) of the FACT Act revises the definition of ''medical information'' in section 603(i) to mean information or data, whether oral or recorded, in any form or medium, created by or derived from a health care provider or the consumer, that relates to the past, present, or future physical, mental, or behavioral health or condition of an individual, the provision of health care to an individual, or the payment for the provision of health care to an individual. The term ''medical

information'' does not include the age or gender of a consumer, demographic information about the consumer, including a consumer's residence address or e-mail address, or any other information about a consumer that does not relate to the physical, mental, or behavioral health or condition of a consumer, including the existence or value of any insurance policy.

Section 411(a) also amends the FCRA by adding new section 604(g)(2) to prohibit creditors from obtaining or using medical information pertaining to a consumer in connection with any determination of the consumer's eligibility, or continued eligibility, for credit. Section 604(g)(2) contains two independent prohibitions—a prohibition on obtaining medical information and a prohibition on using medical information. The statute contains no prohibition, however, on creditors obtaining or using medical information other than in connection with a determination of the consumer's eligibility, or continued eligibility, for credit. For example, section 604(g)(2) does not prohibit a creditor from obtaining medical information in connection with employment purposes. Nevertheless, a creditor that obtains medical information in connection with employment purposes may not subsequently use that information in connection with any determination of the consumer's eligibility, or continued eligibility, for credit. Section 604(g)(5)(A) requires the Agencies to prescribe regulations that permit transactions that are determined to be necessary and appropriate to protect legitimate operational, transactional, risk, consumer, and other needs (including administrative verification purposes), consistent with Congressional intent to restrict the use of medical information for inappropriate purposes.

Section 411(b) of the FACT Act adds a new section 603(d)(3) to the FCRA to restrict the sharing of medically related information with affiliates if that information meets the definition of ''consumer report'' in section 603(d)(1) of the FCRA. Specifically, section 603(d)(3) provides that the standard exclusions from the definition of ''consumer report'' contained in section 603(d)(2)—such as sharing transaction or experience information among affiliates or sharing other information among affiliates after notice and an opportunity to opt-out—do not apply if medically related information is disclosed to an affiliate. Medically related information includes medical information, as described above, as well as an individualized list or description based on payment transactions for medical products or services, and an aggregate list of identified consumers based on payment transactions for medical products or services.

Section 604(g)(3), however, provides several exceptions that allow institutions to share medically related information with affiliates in accordance with the standard exclusions that apply to the sharing of non-medically related information. These exceptions provide that an institution may share medically related information with an affiliate without having the communication categorically treated as a consumer report if the information is disclosed to an affiliate:

(1) In connection with the business of insurance or annuities (including the activities described in section 18B of the model Privacy of Consumer Financial and Health Information Regulation issued by the National Association of Insurance Commissioners, as in effect on January 1, 2003);

(2) For any purpose permitted without authorization under the Standards for Individually Identifiable Health Information promulgated by the Department of Health and Human Services (HHS) pursuant to the Health Insurance Portability and Accountability Act of 1996 (HIPAA);

(3) For any purpose referred to under section 1179 of HIPAA;

(4) For any purpose described in section 502(e) of the Gramm-Leach-Bliley Act; or

(5) As otherwise determined to be necessary and appropriate, by regulation or order, by the Federal Trade Commission (FTC), the Agencies, or an applicable State insurance authority.

Section 604(g)(4), as added by section 411(a)(4) of the FACT Act, also provides that any person that receives medical information from an affiliate pursuant to an exception in section 604(g)(3) or from a consumer reporting agency under section 604(g)(1) must not disclose such information to any other person, except as necessary to carry out the purpose for which the information was initially disclosed, or as otherwise permitted by statute, regulation, or order.

II. Overview of Comments Received

On April 28, 2004, the Agencies published a notice of proposed rulemaking in the **Federal Register** (69 FR 23380) to implement the provisions of section 411 of the FACT Act. The Agencies proposed to create exceptions to the general prohibition against creditors obtaining or using medical information in connection with credit eligibility determinations, as required by section 604(g)(5)(A), to permit transactions necessary and appropriate to protect legitimate operational, transactional, risk, consumer, and other needs (including administrative verification purposes), consistent with the intent of Congress to restrict the use of medical information for inappropriate purposes. In addition, the Agencies proposed to create additional exceptions to the special restrictions in section 603(d)(3) on sharing medically related information with affiliates, as permitted by section 604(g)(3)(C).

Each of the Agencies received up to 40 comment letters in response to the proposal, although many commenters sent copies of the same letter to more than one Agency. Comments were received from a variety of industry commenters, including banks, thrifts, credit unions, credit card companies, mortgage lenders and other non-bank creditors, and industry trade associations. Comments were also received from insurance companies and insurance industry trade associations. Other comments were received from consumer and community groups, privacy advocates, and health care associations. A comment letter was received from two Members of Congress, and another comment letter was received from the Federal Trade Commission.

Most commenters supported the proposed rule. Commenters offered a number of suggested changes, with the most common suggestions including: broadening the scope of coverage to apply to all creditors; broadening the scope of coverage to apply to an individual's credit eligibility made in connection with business credit; clarifying the definition of ''medical information'; implementing the statute by relying primarily on interpretations of the statute rather than exceptions; addressing debt cancellation contracts, debt suspension agreements, and credit insurance products through an exception; and revising the language and scope of various exceptions to the general prohibition on obtaining and using medical information.

The Agencies have modified the proposed rule in light of the comments received. These comments, and the Agencies' responses to the comments, are discussed in the following section-by-section analysis. As discussed below, the Agencies are adopting these rules as interim final rules so that interested parties may comment on the expanded scope of the exceptions for obtaining and using medical information in connection with credit eligibility determinations.

III. Section-by-Section Analysis

Section __.2 Examples

Section __.2 of the proposal discussed the scope and effect of the examples included in the proposed rule. Commenters supported the provision regarding the scope and effect of examples. Section __.2 is therefore adopted as proposed.

Section __.3 Definitions

Section __.3 of the proposal contained definitions for the terms ''affiliate'' (as well as the related terms ''company'' and ''control''), ''consumer,'' ''medical information,'' and ''you.'' The proposed definition of ''you'' has not been included in the interim final rule as unnecessary.[1]

Affiliate

Several FCRA provisions apply to information sharing with persons ''related by common ownership or affiliated by corporate control,'' ''related by common ownership or affiliated by common corporate control,'' or ''affiliated by common ownership or common corporate control.'' *E.g.*, FCRA, sections 603(d)(2), 615(b)(2), and 624(b)(2). Each of these provisions was enacted as part of the 1996 amendments to the FCRA. Similarly, section 2 of the FACT Act defines the term ''affiliate'' to mean persons that are related by common ownership or affiliated by corporate control.

Under the proposal, the Agencies proposed to define ''affiliate'' to mean any company that controls, is controlled by, or is under common control with another company, which is identical to the definition of ''affiliate'' in section 509 of the GLB Act and the GLB Act privacy regulations. The Agencies received very few comments on the definition of ''affiliate'' and none that suggested changes to the definition.

In the interim final rules, the Agencies have revised the definition of ''affiliate'' to track more closely the definition contained in section 2 of the FACT Act. Section __.3(b) of the interim final rules defines ''affiliate'' to mean any company that is related by common ownership or common corporate control with another company.[2]

The Agencies believe there is no substantive difference between the FACT Act definition of ''affiliate'' and the definition of ''affiliate'' in section 509 of the GLB Act. The Agencies are not aware of any circumstances in which two entities would be affiliates for purposes of the FCRA but not for purposes of the GLB Act privacy rules, or vice versa. Furthermore, even though affiliated entities have had to comply with different formulations of the ''affiliate'' definition under the FCRA and the GLB Act since 1999, the Agencies are not aware of any compliance difficulties or disputes resulting from the two statutes using somewhat different wording to describe what constitutes an affiliate.

Under the GLB Act privacy rules, the definition of ''control'' determines whether two or more entities meet the definition of ''affiliate.''[3] The Agencies included the same definition of ''control'' in the proposal. The Agencies received no comments on the proposed definition of ''control.'' Accordingly, the Agencies interpret the phrase ''related by common ownership or common corporate control'' as used in the FACT Act to have the same meaning as ''control'' in the GLB Act privacy rules. For example, if an individual owns 25 percent of two companies, the companies would be affiliates under both the GLB Act and FCRA definitions. However, the individual would not be considered an affiliate of the companies because the definition of ''affiliate'' is limited to companies.

For purposes of clarity, the Agencies are revising the defined term from ''control'' (as in the proposal) to ''common ownership or common corporate control'' in order to track more closely the terminology used in the FACT Act.[4] In addition, the Agencies believe that certain types of persons, for example, governments or governmental agencies or individuals are not subject to control, as that term is defined in the interim final rules, for purposes of defining an affiliate.

The proposal also included a definition of ''company,'' which was defined to include any corporation, limited liability company, business trust, general or limited partnership, association, or similar organization. Omitted from the definition of ''company'' are some entities that are ''persons'' under the FCRA, including estates, cooperatives, and governments or governmental subdivisions or agencies, as well as individuals. The Agencies received no comments on the proposed definition of ''company,'' which is adopted as proposed.

The interim final rule includes a definition of ''person'' to reflect that the definition of ''affiliate'' now refers to a ''person'' rather than to a ''company.'' The definition of ''person'' tracks the statutory definition and means any individual, partnership, corporation, trust, estate, cooperative, association, government or governmental subdivision or agency, or other entity.

Medical Information

Under the proposed rule, paragraph (k) defined the term ''medical information'' to mean information or data, whether oral or recorded, in any form or medium, created by or derived from a health care provider or the consumer, that relates to (1) the past, present, or future physical, mental, or behavioral health or condition of an individual; (2) the provision of health care to an individual; or (3) the payment for the provision of health care to an individual. Proposed paragraph (k) also made clear that the term ''medical information'' did not include the age or gender of a consumer, demographic information about the consumer, including a consumer's residence address or e-mail address, or any other information about a consumer that does not relate to the physical, mental, or behavioral health or condition of a consumer, including the existence or value of any insurance policy. The definition in the proposal tracked the statutory definition of ''medical information.''

The Agencies requested comment on whether coded information furnished by a consumer reporting agency in accordance with section 604(g)(1)(C) of the FCRA should be deemed to fall outside the definition of ''medical information.'' Industry commenters generally believed that coded information should be excluded from the definition of ''medical information'' because Congress, by requiring coding by consumer reporting agencies, determined the appropriate protection for this information. Privacy advocates, consumer and community groups, and health care associations urged the Agencies not to exclude coded information from the definition of ''medical information'' because they believed it would be an inappropriate narrowing of the statutory definition and would effectively remove such information from the anti-discrimination protections of proposed § __.30(c) by allowing creditors to treat medical debts, if coded, differently than non-medical debts. Based on the

[1] The OTS previously added a definition of ''you'' to § 571.3(o) in connection with its disposal rule. *See* 69 FR 77610, 77621 (Dec. 28, 2004). That definition remains in the OTS's rule.

[2] For purposes of the regulation, an ''affiliate'' includes an operating subsidiary of a bank or savings association, and a credit union service organization that is controlled by a Federal credit union.

[3] *See* 12 CFR 40.3(g), 216.3(g), 332.3(g), 573.3(g), and 716.3(g).

[4] For purposes of the regulation, NCUA presumes that a Federal credit union has a controlling influence over the management or policies of a credit union service organization if it is 67 percent owned by credit unions.

comments received and an analysis of the terms and structure of the FACT Act, the Agencies have determined to treat coded information as ''medical information'' for purposes of the Agencies'' rules. The statutory definition of ''medical information'' is quite broad. In addition, the wording of section 604(g)(1) indicates that ''medical information about a consumer'' includes both coded and uncoded information from a consumer report. How creditors may obtain and use this information is discussed below.

A number of commenters asked the Agencies to clarify that ''medical information'' must relate or pertain to a specific consumer. Commenters requested this clarification to ensure that creditors can continue to use databases containing aggregate, non-personally identifiable information about consumers to analyze consumer behavior patterns without violating the restrictions on obtaining or using medical information. The FTC recommended that the Agencies clarify that information about collateral is not ''medical information'' because information about collateral does not pertain to an individual.

The Agencies believe that the statutory definition of ''medical information'' applies only to information that is associated with a specific consumer because such information must relate to the condition ''of an individual'' or the provision of health care or payment for the provision of health care ''to an individual.'' In the interim final rule, the Agencies have clarified that the term ''medical information'' does not include information that does not identify a specific consumer. Section __.3(k)(2)(iv) contains this clarification. The interim final rule does not categorically exclude information about collateral from the definition of medical information because the relationship between information about collateral and medical information about an individual may depend upon the facts and circumstances.

One commenter asked the Agencies to clarify that information about the death of an individual is not medical information. The Agencies believe that the fact that a consumer is deceased generally is not ''medical information.'' However, certain information associated with the death of a consumer, such as information about the medical condition that resulted in the consumer's death, may be medical information.

Creditors are reminded that other laws, such as the Americans with Disabilities Act, the Fair Housing Act (FHA), the GLB Act, the Health Insurance Portability and Accountability Act (HIPAA), and other parts of the FCRA, may limit or regulate the use, collection, and sharing of consumer information, including medical information. These and other laws, such as the Equal Credit Opportunity Act (ECOA), also may prohibit creditors from using certain information that is excluded from the restrictions on obtaining or using medical information, such as age or gender information, in determining eligibility for credit or for other purposes. The exceptions created by this rule do not override or modify, or in any way limit the responsibility of creditors to comply with all applicable Federal and state fair lending laws. The OTS reminds creditors subject to its rules that they must comply with the requirements of the OTS's anti-discrimination rules when seeking to obtain and use medical information in reliance on the exceptions in this rule.[5]

Section __.30 Obtaining or Using Medical Information in Connection With a Determination of Eligibility for Credit

Section 411(a) of the FACT Act adds a new section 604(g)(2) to the FCRA, which contains a broad new limitation on the ability of creditors to either obtain or use medical information in connection with credit eligibility determinations.

A. Scope of Rules on Obtaining or Using Medical Information

Section 604(g)(2) (as added by section 411 of the FACT Act) prohibits any ''creditor'' from obtaining or using ''medical information'' in connection with any determination of the consumer's eligibility, or continued eligibility, for credit.[6] The definition of ''medical information'' adopted in the FACT Act broadly includes information or data, whether oral or recorded, in any form or medium, created by or derived from a health care provider or a consumer that relates to the past, present, or future physical, mental, or behavioral health or condition of an individual, the provision of health care to an individual, or the payment for the provision of health care to an individual.[7] The definition encompasses important financial information about consumers that is typically used in the credit underwriting process, such as information about the payment history and status of medical debts and the amount of a consumer's disability income.

Section 111 of the FACT Act added a definition of ''creditor'' to the FCRA that is also very broad and includes any person who regularly extends, renews, or continues credit, any person who regularly arranges for the extension, renewal, or continuation of credit, or any assignee of an original creditor who participates in the decision to extend, renew, or continue credit.[8] A ''creditor'' includes depository institutions as well as entities that are neither depository institutions nor affiliates of depository institutions, such as independent finance companies, loan brokers, health care providers, and automobile dealers. Accordingly, section 604(g)(2) prohibits all creditors from obtaining or using key financial information that is also medical information in the credit underwriting process.

Section 604(g) does not contain any specific statutory exception to this broad prohibition. Instead, section 604(g)(5) directs the Agencies to prescribe regulations to permit ''transactions'' in which creditors obtain or use medical information that are ''necessary and appropriate to protect legitimate operational, transactional, risk, consumer, and other needs consistent with the intent of paragraph (2) to restrict the use of medical information for inappropriate purposes.''[9] Section 604(g)(5) does not by its terms limit the scope of the creditors that may rely on exceptions granted by the Agencies.

Proposed § __.1(b)(2) identified the persons to which the rules relating to obtaining and using medical information in proposed §§ __.30(a)–(d) applied. As proposed, each Agency's rule and the exceptions created by those rules applied to creditors subject to the regulatory jurisdiction of the respective Agency. The most significant issue raised by commenters in connection with the proposal related to the classes of creditors to which the exceptions to the statutory prohibition in section 604(g)(2) would apply. Many commenters strongly urged the Agencies to make clear that the regulatory exceptions apply to *all* creditors that are subject to the statutory prohibition on

[5] The OTS's anti-discrimination regulations are found at 12 CFR part 528.

[6] 15 U.S.C. 1681b(g)(2).

[7] *Id.* at § 1681a(i). ''Medical information'' does not include the age or gender of a consumer, demographic information about the consumer, including a consumer's residence address or e-mail address, or any other information about a consumer that does not relate to the physical, mental, or behavioral health or condition of a consumer, including the existence or value of any insurance policy. *Id.*

[8] The meaning of ''creditor'' in the FCRA has the same meaning as in the Equal Credit Opportunity Act (''ECOA''). *Id.* at §§ 1681a(r)(5) and 1691a(e).

[9] *Id.* at § 1681b(g)(5)(A).

obtaining or using medical information, not just bank and thrift creditors and their affiliates and Federal credit unions. Many financial institution creditors indicated that, if the exceptions failed to apply to all creditors, the lending activities of financial institutions would be adversely affected because financial institutions often originate loans through, or purchase loans from, persons that are creditors for purposes of the FCRA but are not financial institutions. In particular, commenters noted that arrangers of credit (which are creditors for purposes of the FCRA) may include doctors and other health care providers that inform consumers of medical financing options and act as a liaison between the consumer and the creditor.

Finally, commenters argued that, without clarification that the classes of creditors that could rely on the Agencies' regulatory exceptions were the same as the classes of creditors subject to the statutory prohibition, a significant number of creditors unaffiliated with banks, thrifts, or Federal credit unions would be in doubt about their ability to obtain and use excepted medical information in the same way and to the same extent as the Agencies' rules allow creditors that are banks, thrifts, Federal credit unions, or affiliates of those institutions to obtain and use the identical information. This result could reduce the availability of credit generally because of the breadth of the statute's definition of medical information. Two Members of Congress who sponsored section 411 of the FACT Act, submitted a comment letter supporting this view and indicating that it was their intention that the exceptions would apply to non-bank finance companies, state-chartered credit unions, and doctors, medical suppliers, and other medical professionals.

The prohibition on creditors obtaining or using medical information in connection with credit eligibility determinations in section 604(g)(2) applies to all creditors. As noted above, section 605(g)(5) does not, by its terms, limit the creditors that may rely on the exceptions granted by the Agencies. Moreover, that section, by its terms, applies to ''transactions'' for which the Agencies determine exceptions are necessary, not to ''creditors'' that the Agencies determine must be protected by the exceptions. Accordingly, the combined scope of the exceptions adopted pursuant to section 604(g)(5) in the interim final rules is as broad as the prohibition to which it applies, and is available to all creditors.

The final action is comprised of six rules. The applicability of the section of each Agency's rule addressing the prohibition on and exceptions for creditors obtaining or using medical information in connection with credit eligibility determinations is set forth in § __.30(a) and covers transactions in which certain enumerated entities participate as creditors. Under § __.30(a)(2), other entities that participate as creditors in transactions in which an enumerated entity also participates as a creditor are also subject to that Agency's rule.

In addition, a separate rule, codified in part 232 of the Board's chapter of the *Code of Federal Regulations* (hereafter ''separate rule''), affords the exceptions to the prohibition against obtaining and using medical information for credit eligibility determinations generally to all creditors, except for creditors that are subject to one of the other Agencies' rules. This combination of rules establishes uniform coverage and exceptions for transactions involving any creditor that is subject to the prohibition on obtaining or using medical information in section 411. The separate rule has been located in the Board's chapter of the Code of Federal Regulations as a matter of convenience because many creditors are accustomed to looking to the Board's regulations implementing other statutes, such as the Truth-in-Lending Act and the Equal Credit Opportunity Act.

The Agencies believe it is important that rules prescribing exceptions to the prohibitions from obtaining or using medical information in connection with credit eligibility determinations be consistent. Thus, in developing the proposed and interim final rules, the Agencies have consulted and coordinated with each other to establish identical rules. The Agencies will consult and coordinate with each other regarding any amendments to the rules for the purpose of assuring, to the extent possible, that the regulations prescribed by each Agency remain consistent and comparable with the regulations prescribed by the other Agencies.

These rules are being adopted on an interim final basis with a delayed effective date. While a number of commenters urged clarification of the scope of the availability of the exceptions, the Agencies are concerned that uncertainty about this matter may have led creditors that believed they could not avail themselves of the exceptions not to comment on the appropriateness and details of the exceptions.

B. General Prohibition on Obtaining or Using Medical Information

Proposed paragraph (a)(1) incorporated the statute's general rule prohibiting creditors from obtaining or using medical information pertaining to a consumer in connection with any determination of a consumer's eligibility, or continued eligibility, for credit, except as provided in the regulations under subpart D. The supplementary information to the proposal noted the consumer's eligibility for credit typically would be determined when an initial decision is made on whether to grant or deny credit to the consumer, but could also include decisions whether to terminate an account or adjust a credit limit following an account review. The Agencies received no comments on this restatement of the statutory prohibition in the proposal. Renumbered paragraph (b)(1) in each Agency's rule and § __.1(b) of the separate rule contain this provision, which is adopted as proposed.

Proposed paragraph (a)(2) clarified the meaning of certain terms used in the statutory prohibition and the proposed rule, including ''eligibility, or continued eligibility, for credit,'' ''credit,'' and ''creditor.'' Commenters had no comments on the definitions of ''credit'' and ''creditor,'' which tracked the FACT Act's definition of those terms. In the interim final rule, renumbered paragraphs (b)(2)(i) and (ii) of each Agency's rule and § __.1(c)(2) and (3) of the separate rule contain the definitions of ''credit'' and ''creditor,'' which are adopted as proposed.

The proposed rule interpreted the phrase ''eligibility, or continued eligibility, for credit'' to mean the consumer's qualification or fitness to receive, or continue to receive, credit, including the terms on which credit is offered, primarily for personal, family, or household purposes. The proposal further clarified that the phrase ''eligibility, or continued eligibility, for credit'' did not include the following: (1) The consumer's qualification or fitness to be offered employment, insurance products, or other non-credit products or services; (2) a determination of whether the provisions of a debt cancellation contract, debt suspension agreement, credit insurance product, or similar forbearance practice or program are triggered; (3) authorizing, processing, or documenting a payment or transaction on behalf of a consumer in a manner that does not involve a determination of the consumer's eligibility, or continued eligibility, for credit; or (4) maintaining or servicing a

consumer's account in a manner that does not involve a determination of the consumer's eligibility, or continued eligibility, for credit.

Commenters offered a substantial number of suggestions regarding the meaning of ''eligibility, or continued eligibility, for credit.'' Industry commenters supported limiting the term to credit primarily for personal, family, or household purposes consistent with the traditional scope of the FCRA. Privacy advocates, consumer and community groups, and health care associations, on the other hand, objected to the exclusion of business credit from the general prohibition on obtaining or using medical information. These commenters argued that the proposed limitation to consumer credit conflicted with the FCRA definitions of ''credit'' and ''creditor,'' which incorporate the ECOA definitions of those terms. Moreover, these commenters noted that Congress initially used the Truth in Lending Act (TILA) definitions of ''credit'' and ''creditor'' in the draft FACT Act legislation, but subsequently adopted the ECOA definitions of those terms. ECOA applies to business purpose credit, whereas TILA does not.

The Federal banking agencies (OCC, Board, FDIC, and OTS) have previously taken the position that a creditor has a permissible purpose to obtain a consumer report on a consumer in connection with a business credit transaction under section 604(a)(3)(A) of the FCRA if the consumer is or will be personally liable on the loan, such as in the case of a guarantor, co-signer, or, in most instances, an individual proprietor. An informal FTC staff opinion letter concurred with the banking agencies' position. *See* Letter from Joel Winston to Julie L. Williams, J. Virgil Mattingly, William F. Kroener, III, and Carolyn Buck, June 22, 2001. A copy of this letter is available from the FTC's Internet Web site at *http://www.ftc.gov/os/statutes/fcra/tatelbaum2.htm.* To ensure consistency with the prior interpretation, the Agencies are deleting the phrase ''primarily for personal, family, or household purposes'' from the definition of ''eligibility, or continued eligibility, for credit.'' In order for the prohibition in section 604(g)(3) to apply, a creditor must obtain or use medical information about a consumer in connection with a determination of a consumer's eligibility, or continued eligibility, for credit. Accordingly, the general prohibition would apply to business credit if a consumer would be personally liable for repayment of a business loan.

Commenters also pointed to an ambiguity in the proposal: proposed paragraph (a)(2)(i)(A) referred to insurance products while proposed paragraph (a)(2)(i)(B) referred to credit insurance products. To eliminate this ambiguity, the interim final rule has been revised so that renumbered paragraph (b)(2)(iii)(A) of each Agency's rule and section __.1(c)(4)(i) of the separate rule applies to insurance products other than credit insurance products. Additional, non-substantive changes have been made to these paragraphs for clarity.

Commenters made a number of suggestions regarding debt cancellation contracts, debt suspension agreements, and credit insurance products, which were addressed in proposed paragraph (a)(2)(i)(B). Most commenters believed that these contracts, agreements, and products should be addressed through an exception, rather than through an interpretation. In the interim final rule, debt cancellation contracts, debt suspension agreements, and credit insurance products are addressed in two new exceptions, which are discussed below.

Forbearance practices or programs were also addressed in proposed paragraph (a)(2)(i)(B). Most commenters believed that forbearance practices and programs should be addressed through an exception, rather than through an interpretation. In the interim final rule, forbearance practices or programs are addressed in a new exception, which is discussed below.

Under the proposal, the term ''eligibility, or continued eligibility, for credit'' did not include authorizing, processing, or documenting a payment or transaction on behalf of a consumer in a manner that does not involve a determination of the consumer's eligibility, or continued eligibility, for credit. The interim final rule retains this interpretation in paragraph (b)(2)(iii)(B). *See also* section __.1(c)(4)(ii) of the separate rule. A few commenters asked the Agencies to clarify that over limit transactions or fees and the use of transaction codes fall within this interpretation. Typically, the routine processing of over limit transactions or the imposition of over limit fees would not involve a determination of the consumer's eligibility, or continued eligibility, for credit. If, however, a creditor has medical information about the consumer and uses that information to determine whether or not to raise the consumer's credit limit, such use must fall within an exception in §§__.30(d) or (e) of each Agency's rule or §§__.3 or __.4 of the separate rule to be permissible. Similarly, the use of transaction codes that identify payments to merchants of medical products or services typically would not involve a determination of the consumer's eligibility, or continued eligibility, for credit, unless the creditor uses the medically related codes to make a judgment about whether, and on what terms, to extend credit to the consumer.

Under the proposal, the term ''eligibility, or continued eligibility, for credit'' did not include maintaining or servicing a consumer's account in a manner that does not involve a determination of the consumer's eligibility, or continued eligibility, for credit. The interim final rule retains this interpretation in paragraph (b)(2)(iii)(C) of each Agency's rule. *See also* section __.1(c)(4)(iii) of the separate rule.

The FTC recommended adding a number of additional interpretations and deleting or revising references suggesting that the proposed interpretations and rule of construction were not statutory interpretations. In the interim final rule, the Agencies have deleted references that may have suggested that the interpretations are not interpretations of the statute. Most of the additional interpretations recommended by the FTC are addressed elsewhere in this preamble.

One FTC suggestion not addressed elsewhere is the recommendation to interpret the statute to permit doctors and other providers of medical goods and services to extend credit to consumers where the credit is incidental to the provision of medical goods or services. The Agencies agree that providers of medical goods and services ordinarily would obtain medical information pertaining to a consumer in connection with rendering medical care, and not in connection with credit eligibility decisions. Moreover, if a provider did not use that medical information in connection with determining the consumer's eligibility to receive credit, then the provider clearly would not violate the prohibition. For example, a doctor who treats a patient before billing the patient for her services, without considering the patient's payment history or other medical information relating to the patient, would not have obtained and used medical information in connection with an eligibility determination for credit.

As discussed above, the definition of medical information is very broad and includes not only the health or condition of an individual, but information relating to the payment for the provision of health care. *See* section 603(i) of the FCRA (15 U.S.C. 1681a(i)). If a provider uses medical information,

such as a consumer's history of not paying medical bills promptly, in determining whether and on what terms to extend credit to the consumer, then the provider, as a creditor, has used medical information in connection with a credit eligibility determination in contravention of the general prohibition. Thus, the Agencies conclude that an interpretation that excludes incidental credit from the statutory prohibition is not supported by the statute because medical service providers that extend incidental credit may, in some instances, use medical information to determine the consumer's eligibility for such credit.

C. Receiving Unsolicited Medical Information and Coded and Uncoded Information from a Consumer Reporting Agency

Section __.30(b) of the proposal contained a rule of construction regarding the receipt of unsolicited medical information in recognition of the fact that creditors may receive medical information without specifically asking for it. A creditor may receive unsolicited medical information, for example, when a consumer informs the loan officer that she needs a loan to pay for treatment for a particular medical condition, or when a consumer, in response to a general request on a credit application for information about outstanding debts, lists debts owed to hospitals and doctors for medical services. The Agencies proposed a rule of construction to make clear that a creditor would not violate the prohibition on obtaining medical information if the creditor received medical information without specifically asking for or requesting such information and did not use it.

Commenters generally supported the rule of construction for unsolicited medical information. Industry commenters generally favored a rule of construction over an exception.

In addition, the Agencies solicited comment on how to treat information in consumer reports containing information described in section 604(g)(1) of the FCRA. The Agencies solicited comment on three options for allowing creditors to obtain and use coded information contained in a consumer report pursuant to section 604(g)(1)(C). One approach was to interpret ''medical information'' to exclude coded information that may be furnished under section 604(g)(1)(C) of the Act. Another approach was to interpret the prohibition on obtaining or using medical information in section 604(g)(2) as qualified by the provisions in section 604(g)(1) that authorize consumer reporting agencies to furnish consumer reports containing medical information under certain circumstances. A final approach was to require creditors that intend to obtain and use coded medical information in connection with credit eligibility determinations to do so in accordance with the financial information exception in proposed §__.30(c).

Industry commenters generally believed that coded information should be excluded from the definition of ''medical information.'' Privacy advocates, consumer and community groups, and health care associations, on the other hand, maintained that coded information fell within the definition of ''medical information'' and opposed the creation of a separate consumer report exception as in proposed paragraph (d)(1)(iii). These commenters believed that the other proposed exceptions were sufficient to protect legitimate uses of both coded and uncoded medical information obtained from a consumer report. The FTC urged the Agencies to interpret the general prohibition on creditors obtaining and using medical information in section 604(g)(2) as qualified by the provisions in section 604(g)(1) applicable to consumer reporting agencies that furnish consumer reports containing medical information.

As noted above, the Agencies interpret coded information provided pursuant to section 604(g)(1)(C) as meeting the broad statutory definition of ''medical information.'' Under the interim final rules, a creditor that receives medical information from a consumer reporting agency, whether coded or uncoded, without specifically requesting that information does not obtain medical information in violation of the prohibition. Such information, however, may be used only in accordance with the exceptions contained in renumbered paragraphs 30(d) or (e) of each Agency's rule or §§__.3 or __.4 of the separate rule.

The proposal also included a separate exception for uncoded medical information furnished by a consumer reporting agency in a consumer report pursuant to section 604(g)(1)(B) in proposed paragraph (d)(1)(iii). The proposed exception has been omitted from the interim final rule as unnecessary. Commenters generally did not support this exception. A number of these commenters believed that the other exceptions were sufficient and that no separate exception should be created for consumer reports. The FTC urged the Agencies to treat coded and uncoded medical information furnished by consumer reporting agencies the same by interpreting the general statutory prohibition as inapplicable to such information.

The Agencies believe that the exceptions in renumbered paragraphs (d) and (e) of each Agency's rule and in §§__.3 and __.4 of the separate rule provide creditors sufficient flexibility with respect to the use of medical information contained in consumer reports. The rule of construction for unsolicited medical information adequately protects creditors that receive coded or uncoded medical information in consumer reports furnished by consumer reporting agencies without specifically requesting medical information. If, however, a creditor specifically requests medical information from a consumer reporting agency in connection with a credit eligibility determination, the creditor must meet one of the exceptions in renumbered paragraphs (d) and (e) of each Agency's rule or §§__.3 and __.4 of the separate rule in order to obtain and use that information.

Renumbered paragraph (c) of the interim final rule adopts the rule of construction for unsolicited medical information with certain revisions. Section __.2 of the separate rule contains the identical provision. The interim final rule provides that a creditor does not *obtain* medical information in violation of the prohibition if it receives such information from a consumer, a consumer reporting agency, or any other person in connection with any determination of the consumer's eligibility, or continued eligibility, for credit without specifically requesting medical information. The rule of construction is retained as an interpretation, rather than as an exception because it interprets the statutory language regarding when a creditor ''obtains'' medical information in violation of the prohibition.

The introductory language to the rule of construction has been revised for clarity to provide that a creditor does not obtain medical information ''in violation of the prohibition'' if it meets the specified criteria. In addition, the cross-reference to the general prohibition has been deleted because the rule of construction is an interpretation of the statute.

Proposed paragraph (b)(1)(ii), which prohibited the use of unsolicited medical information, has been deleted because the rule of construction focuses on when a creditor does not obtain medical information in violation of the statute. The Agencies believe that incorporating a use limitation in the rule of construction would be

inconsistent with the exceptions in renumbered paragraphs (d) and (e). Instead, the Agencies have added a new paragraph (c)(2) to clarify that a creditor that receives unsolicited medical information may use that information in connection with any determination of the consumer's eligibility, or continued eligibility, for credit only to the extent the creditor can rely on one of the exceptions in renumbered paragraphs (d) or (e).

The examples of the rule of construction have been moved to renumbered paragraph (c)(3) in the interim final rules and all references to restrictions on the use of unsolicited medical information have been deleted from the examples consistent with the changes discussed above. In addition, paragraph (c)(3)(iii) adds a new example to illustrate how the rule of construction applies to medical information furnished by a consumer reporting agency.

Commenters had several other comments concerning the rule of construction. Privacy advocates, consumer and community groups, and health care associations suggested that the Agencies clarify that the phrase ''without specifically requesting medical information'' means information obtained voluntarily without any pressure, prompting, or direct or indirect solicitation by the creditor. These commenters also sought an additional requirement that creditors destroy unsolicited medical information as soon as reasonably practicable and suggested making the rule of construction an exception. Some industry commenters suggested that consumers should have the burden of proving that unsolicited medical information was used in a credit eligibility determination because it may be difficult for creditors to prove that unsolicited medical information was not used. Some industry commenters suggested permitting a creditor to use unsolicited medical information in a manner no less favorably than it would use comparable medical information.

The statute does not specifically address the burden of proof to be applied when disputes arise regarding the use of medical information. The Agencies find it unnecessary to address this issue because the interim final rule allows unsolicited medical information to be used as permitted by the exceptions in renumbered paragraphs (d) and (e). The Agencies thus decline to impose on consumers the burden of proving that unsolicited medical information was used in a credit eligibility determination. Furthermore, even if the consumer requests that a creditor use unsolicited medical information in connection with a credit eligibility determination, the creditor is not required to do so. The phrase ''without specifically requesting medical information'' along with the examples makes clear that the rule of construction does not apply to medical information obtained through a specific request or solicitation for such information. No further clarification is necessary. The destruction of unsolicited medical information would not be appropriate in many circumstances, thus the Agencies decline to adopt such a rule.

D. Financial Information Exception for Obtaining and Using Medical Information

As noted above, section 604(g)(5)(A) of the Act gives the Agencies the authority to prescribe regulations, after notice and opportunity for comment, to permit transactions in which creditors may obtain and use medical information in connection with determinations of credit eligibility that the Agencies determine to be necessary and appropriate to protect legitimate operational, transactional, risk, consumer, and other needs (including actions necessary for administrative verification purposes), consistent with the intent of the statute to restrict the use of medical information for inappropriate purposes. Applying this standard, the Agencies proposed a number of exceptions to the general prohibition on creditors obtaining or using medical information in connection with credit eligibility determinations. The exceptions were contained in proposed paragraphs (c)–(d). In the interim final rule, these exceptions are contained in renumbered paragraphs (d) and (e) of each Agency's rule and in §§__.3 and __.4 of the separate rule.

Section __.30(c) of the proposal contained the proposed financial information exception. Proposed paragraph (c)(1) provided that a creditor may obtain and use medical information pertaining to a consumer in connection with any determination of the consumer's eligibility, or continued eligibility, for credit so long as the following three elements were met. First, the information must relate to debts, expenses, income, benefits, collateral, or the purpose of the loan, including the use of proceeds. Second, the creditor must use the information in a manner and to an extent no less favorable than it would use comparable information that is not medical information in a credit transaction. Third, the creditor must not take the consumer's physical, mental, or behavioral health, condition or history, type of treatment, or prognosis into account as part of any such determination of credit eligibility.

Commenters generally supported the proposed three-part test for the financial information exception. Privacy advocates, consumer and community groups, and health care associations suggested limiting the exception to circumstances where the creditor has not specifically requested medical information on its application for credit, but rather has made a generic request for financial information. These commenters also suggested including the phrase ''financial information'' in the text of the rule. Industry commenters suggested revising the first prong to apply to a non-exclusive list of information routinely used in the underwriting process. These commenters noted that the Agencies may have unintentionally omitted certain items, such as assets, that should be included in the list. Commenters generally supported the second prong of the test. One commenter suggested that the third prong of the test was inconsistent with and undermined the ''no less favorable'' principle set forth in the second prong and could prove detrimental to consumers. Another commenter found the three-part test complicated and difficult to implement.

The interim final rule retains the three-part test for the financial information exception, with certain modifications. The Agencies agree with those commenters that believe the better approach is to have a non-exclusive list of types of information that are routinely used in making credit eligibility determinations. The first prong of the test, therefore, has been revised to include all information of the type routinely used in making credit eligibility determinations and provides a non-exclusive list of such types of information (*i.e.*, information relating to debts, expenses, income, benefits, assets, collateral, or the purpose of the loan, including the use of proceeds). The Agencies do not believe it would be helpful to include the words ''financial information'' in the text of the exception because there is no bright line between financial information and medical information.

The second prong of the test is adopted as proposed. Commenters appeared comfortable with requiring a creditor to use medical information in a manner and to an extent no less favorable than it would use comparable non-medical information in a credit transaction. As noted in the proposal, a creditor may deny credit to the

consumer because the consumer owes a debt to a hospital if the creditor would have denied credit to the consumer if the consumer had owed the same amount of debt with the same payment history to a retailer. Nothing in the rule prevents the creditor from treating information about medical debts (or expenses or income) more favorably than non-medical debts.

The third prong of the test is also adopted as proposed. Other, more narrowly focused exceptions, such as the medical accommodation exception, permit a creditor to take the consumer's physical, mental, or behavioral health, condition, or history, type of treatment, or prognosis into account in limited circumstances as part of a consumer's credit eligibility determination. For this type of core medical information, the Agencies believe it is appropriate to more strictly limit the circumstances in which creditors may obtain or use this information.

Since creditors generally are prohibited from obtaining medical information in connection with any determination of the consumer's eligibility, or continued eligibility, for credit, a creditor ordinarily would not specifically request medical information on an application, but would obtain such information in response to a generic question on an application about debts, income, and other information routinely used in credit eligibility determinations. Thus, except where a creditor has a specific application for the financing of medical procedures, a creditor generally would be prohibited from specifically asking for medical information on a credit application.

Proposed paragraph (c)(2) provided several non-exclusive examples to illustrate when creditors may obtain and use medical information under the financial information exception. Commenters generally supported the proposed examples. One commenter requested a clarification of the example in proposed paragraph (c)(2)(iii)(B). In that example, a consumer meets with a loan officer of a creditor to apply for a mortgage loan. While filling out the loan application, the consumer informs the loan officer orally that she has a potentially terminal disease. The consumer meets the creditor's established requirements for the requested mortgage loan. The loan officer recommends to the credit committee that the consumer be denied credit because the consumer has that disease. The commenter recommended adding a statement that the bank acted on the loan officer's recommendation and denied the application because the consumer had a potentially terminal disease to clarify that the creditor, in fact, used medical information in a manner inconsistent with the exception. The Agencies believe this clarification is helpful and, in the interim final rule, have revised the example in renumbered paragraph (d)(2)(iii)(B) of each Agency's rule accordingly. *See also* section __.3(b)(3)(ii) of the separate rule.

In addition, a new example has been added in paragraph (d)(2)(iii)(C) of each Agency's rule and §__.3(b)(3)(iii) of the separate rule to illustrate that a creditor cannot use a consumer's apparent medical condition as the basis for requiring the consumer to obtain debt cancellation, debt suspension, or credit insurance coverage as a condition for the extension of credit. Even though the use of medical information to determine the consumer's eligibility for a debt cancellation contract, debt suspension agreement, or credit insurance product generally is subject to an exception to the general prohibition pursuant to paragraphs (e)(1)(viii) or (e)(1)(ix), a creditor may not condition an extension of credit to the consumer on the consumer obtaining debt cancellation, debt suspension, or credit insurance coverage based on the consumer's physical, mental, or behavioral health, condition or history, type of treatment, or prognosis.

In addition, the heading of renumbered paragraph (d)(2)(i) has been revised in the interim final rule to reflect changes made to the first prong of the test to encompass the type of information routinely used in making credit eligibility determinations. Non-substantive revisions have also been made to the examples in renumbered paragraphs (d)(2)(ii)(A) and (C) for clarity. Aside from these changes, the examples are adopted as proposed.

E. Specific Exceptions for Obtaining and Using Medical Information

Section __.30(d) of the proposal contained a number of specific exceptions to the general prohibition. These exceptions would allow creditors to obtain and use medical information for a limited number of particular purposes in connection with a determination of the consumer's eligibility, or continued eligibility, for credit. A creditor that obtains medical information pursuant to one of these specific exceptions may not subsequently use the information in connection with determining the consumer's eligibility, or continued eligibility, for credit unless an exception applies. In the interim final rule, the specific exceptions are contained in renumbered paragraph (e) of each Agency's rule. Section _.4 of the separate rule contains the identical exceptions in paragraphs (a)(1)–(9).

Determination of power of attorney, legal representative and legal capacity. Proposed paragraph (d)(1)(i) provided that a creditor may obtain and use medical information to determine whether the use of a power of attorney or legal representative is necessary and appropriate. This exception was designed to permit a creditor to verify, in connection with a credit eligibility determination, that the exercise of a power of attorney or legal representative is necessary and appropriate. Some industry commenters suggested that the exception clarify that creditors may obtain and use medical information to determine the consumer's competency or legal capacity to contract. Privacy advocates, consumer and community groups, and health care associations suggested limiting the power of attorney exception to circumstances where a power of attorney is triggered by a medical condition or where there is a legitimate question about the consumer's legal capacity to contract when a person asserts the exercise of a power or attorney or claims to act as a legal representative on behalf of a consumer. The FTC commented that the limited circumstances where medical information may be obtained and used to determine whether a power of attorney is necessary and appropriate would not be in connection with a credit eligibility determination, and therefore should be addressed through an interpretation of the statute, rather than through an exception.

The interim final rule revises the exception for the use of a power of attorney or legal representative. Renumbered paragraph (e)(1)(i) of the interim final rule permits a creditor to obtain and use medical information in connection with determining the consumer's credit eligibility to determine whether the use of a power of attorney or legal representative that is triggered by a medical event or condition is necessary and appropriate or whether the consumer has the legal capacity to contract when a person seeks to exercise a power of attorney or act as legal representative for a consumer based on an asserted medical event or condition. The interim final rule makes two substantive changes in response to the comments received. First, the exception has been narrowed to permit a creditor to obtain and use medical information only when the power of attorney or legal representative is triggered by a medical event or condition. Second, the exception has been revised to permit a creditor to

determine whether the consumer has the legal capacity to contract where a person seeks to exercise a power of attorney or act as a legal representative based on an asserted medical event or condition. This revision is designed to clarify that creditors may obtain and use medical information to verify that the asserted medical event or condition triggering the power of attorney or legal representative has, in fact, occurred and renders the consumer legally incapable of contracting. Where use of a power of attorney or legal representative is triggered by non-medical events or conditions, creditors should not need to obtain or use medical information.

In response to the FTC's comments, the Agencies recognize that a power of attorney or legal representative may be used in a variety of circumstances, many of which have no connection with a determination of a consumer's eligibility, or continued eligibility, for credit. For example, a power of attorney or legal representative may be used in connection with establishing a deposit or other asset account. In those circumstances, the general prohibition on obtaining or using medical information would not apply because the information would not be obtained or used in connection with any determination of the consumer's eligibility, or continued eligibility, for credit. The introductory language to renumbered paragraph (e) of the interim final rules makes clear that the specific exceptions apply to a creditor that ''may obtain and use medical information pertaining to a consumer in connection with any determination of the consumer's eligibility, or continued eligibility, for credit.'' A creditor that obtains and uses medical information in circumstances not connected with a credit eligibility determination is not subject to the general statutory prohibition and does not have to rely upon the power of attorney or any other exception.

Compliance with applicable law. Proposed paragraph (d)(1)(ii) provided an exception to permit a creditor to obtain and use medical information to comply with applicable requirements of local, state, or Federal laws. The Agencies received only a few comments on this proposed exception. One commenter asked the Agencies to clarify that this exception covered laws that prohibit unfair and deceptive acts or practices. The FTC suggested that the financial abuse statutes referenced in the preamble as an example do not involve credit eligibility determinations, and therefore a statutory interpretation was more appropriate than an exception.

In the interim final rule, renumbered paragraph (e)(1)(ii) is adopted as proposed. Although many legal requirements do not have any connection with credit eligibility, other laws may have such a connection. As noted above, a creditor that obtains and uses medical information to comply with applicable laws in circumstances that are not connected with a credit eligibility determination is not subject to the general statutory prohibition and does not have to rely upon the exception. However, the exception is retained to cover those circumstances where it may be needed to protect creditors from inconsistent legal obligations.

Special credit program or credit-related assistance program. One commenter suggested that the proposed compliance with applicable laws exception would not be sufficient to permit creditors to obtain and use medical information in connection with special credit or credit-related programs, such as programs established by government-sponsored enterprises. Such programs may require creditors as part of the program requirements to obtain and use medical information in ways not covered by the other exceptions. Consistent with the policy goals established by Congress, the prohibition on creditors obtaining or using medical information should not interfere with the ability of creditors to assist consumers to qualify for beneficial special programs established by government-sponsored enterprises, not-for-profit organizations, or others.

To address this concern, the interim final rule contains a new exception in renumbered paragraph (e)(1)(iii) that permits creditors to obtain and use medical information in connection with a determination of the consumer's eligibility, or continued eligibility, for credit, to determine, at the consumer's request, whether the consumer qualifies for a legally permissible special credit program or credit-related assistance program that is: (a) Designed to meet the special needs of consumers with medical conditions and (b) established and administered pursuant to a written plan of the plan sponsor that identifies the class of persons that the program is designed to benefit and sets forth the procedures and standards for extending credit or providing other credit-related assistance under the program. Because not all potentially eligible consumers may seek to qualify for a special credit or credit assistance program, this exception applies only when the consumer requests to be considered for the program. A creditor, however, may provide consumers with information about such programs to educate consumers about their options. In addition, any special credit or credit assistance program must meet the requirements of all applicable fair lending laws. The plan sponsor may include a government agency, charitable organization, the creditor, or any other person. This exception is modeled after the provisions relating to special purpose credit programs in the ECOA and the Board's Regulation B, 12 CFR part 202. What programs are permissible and what inquiries to determine medical eligibility are permissible, however, are governed by other laws, including applicable fair lending laws, and are beyond the scope of this rule.

Renumbered paragraph (e)(2) of the interim final rule provides an example to illustrate this exception. In the example, a not-for-profit organization establishes a credit assistance program pursuant to a written plan that is designed to assist disabled veterans purchase homes by subsidizing the down payment for the home purchase mortgage loans of qualifying veterans. The organization works through mortgage lenders and requires mortgage lenders to obtain medical information about the disability of any consumer that seeks to qualify for the program, use that information to verify the consumer's eligibility for the program, and forward that information to the organization. A consumer who is a veteran applies to a creditor for a home purchase mortgage loan. The creditor informs the consumer about the credit assistance program for disabled veterans and the consumer seeks to qualify for the program. The example states that, assuming that the program complies with all applicable law, including applicable fair lending laws, the creditor may obtain and use medical information about the medical condition and disability, if any, of the consumer to determine whether the consumer qualifies for the credit assistance program.

Fraud prevention or detection. Proposed paragraph (d)(1)(iv) provided that a creditor may obtain and use medical information for purposes of fraud prevention and detection. Industry commenters supported the proposed exception. Privacy advocates, consumer and community groups, and health care associations believed the proposed exception was overbroad and unnecessary in light of the other exceptions.

The interim final rule retains the fraud prevention or detection exception in renumbered paragraph (e)(1)(iv), although the language has been revised to make clear that the exception is

available only to the extent necessary to prevent or detect fraud. The Agencies anticipate that creditors would find it necessary to obtain and use medical information for purposes of fraud prevention and detection in limited circumstances. Creditors relying on this exception should have the systems in place to demonstrate the necessity for obtaining and using medical information to prevent or detect fraud. Creditors that actually use medical information in legitimate fraud prevention or detection programs should be able to make this demonstration. Blanket assertions of a fraud prevention or detection purpose alone, however, are not sufficient to justify the collection of medical information about consumers under the anti-fraud exception.

Financing medical products or services. Proposed paragraph (d)(1)(v) provided that a creditor may obtain and use medical information in connection with credit eligibility determinations in the case of credit for the purpose of financing medical products or services to determine and verify the medical purpose of a loan and the use of proceeds. As noted in the proposal, certain creditors have established specialized loan programs that finance specific medical procedures, such as vision correction surgery, but not others. In such cases, the creditor may need to obtain and use medical information in connection with determining whether the purpose of the loan is within the scope of the creditor's established loan program. The proposal also provided examples of this exception.

Commenters generally supported the medical financing exception. Several commenters suggested revising the example in proposed paragraph (d)(2)(i) to permit the creditor to verify that the procedure to be financed will be performed, in conformance with the language of the exception, rather than permitting a creditor to confirm the consumer's medical eligibility.

Renumbered paragraph (e)(1)(v) of the interim final rule retains the medical financing exception as proposed. The examples of the medical financing exception have been moved to paragraph (e)(3) in the interim final rule. The example in paragraph (e)(3)(i) of the interim final rule has been revised from the proposal in accordance with the commenters' suggestions.

Medical accommodation. Section __.30(d)(1)(vi) of the proposal provided that a creditor may obtain and use medical information if the consumer or the consumer's legal representative requested in writing, on a separate document signed by the consumer or the consumer's legal representative, that the creditor use specific medical information for a specific purpose in determining the consumer's eligibility, or continued eligibility, for credit, to accommodate the consumer's particular circumstances. Under the proposal, the signed, written request had to describe the specific medical information that the consumer requested the creditor to use and the specific purpose for which the information would be used. The proposal contemplated an individualized process in which the consumer would inform the creditor about the specific medical information that the consumer would like the creditor to use and for what purpose. As noted in the preamble to the proposal, this exception was not intended to allow creditors to obtain consent on a routine basis or as a part of loan applications or documentation. The proposal provided examples of the medical accommodation exception.

Commenters had a number of recommendations regarding the medical accommodation exception. Privacy advocates, consumer and community groups, and health care associations suggested that the regulation should explicitly state that creditors may not request medical information or consent to obtain medical information on a routine basis or as part of a loan application. Several commenters also suggested clarifying that the request must be voluntary and initiated by the consumer. In addition, commenters suggested including language in the regulation to clarify that the exception is not met by a form that contains a pre-printed description of various types of medical information and the uses to which it might be put. Some commenters urged the Agencies to add a disposal requirement on creditors that obtain information that is not needed. Consumer and community groups also suggested eliminating the forbearance interpretation, folding that interpretation into the medical accommodation exception, and adding anti-discrimination protections to the provision, similar to the ''no less favorable'' standard used in renumbered paragraph (d).

Industry commenters generally believed that the medical accommodation was too restrictive. Some industry commenters suggested that the use of pre-printed consent forms or other routine form of consent should be sufficient to trigger the exception. Other commenters suggested that the consumer should be able to request the use of medical information through oral and electronic means, not simply through a signed writing. One commenter noted that many creditors include a section on their credit applications where the consumer may describe special circumstances or other information that the consumer would like the creditor to consider. This commenter recommended relaxing the requirements of the medical accommodation exception to enable the exception to apply in this circumstance. Another commenter noted that the medical accommodation exception was drafted so narrowly that it may prohibit a creditor from obtaining or using additional medical information to verify or corroborate the facts necessary to support a consumer's medical accommodation request.

In the interim final rule, the medical accommodation exception in renumbered paragraph (e)(1)(vi) has been revised to address commenters' concerns. Paragraph (e)(1)(vi) provides an exception for circumstances where the consumer or the consumer's legal representative specifically requests that the creditor use medical information in determining the consumer's eligibility, or continued eligibility, for credit, to accommodate the consumer's particular circumstances, and such request is documented by the creditor. Any such accommodation must be consistent with safe and sound practices. The requirement for a separate signed writing by the consumer that describes the specific medical information and the specific purpose for which it is to be used has been deleted in the interim final rule. Instead, the interim final rule focuses on the specific request of the consumer and the creditor's documentation of that request. As revised, the interim final rule permits the medical accommodation exception to be triggered by the consumer's oral, electronic, or written request. A consumer may make a specific request by responding to a generic inquiry on a credit application that invites the consumer to describe any special circumstances or other information (not limited to medical information) that the consumer would like the creditor to consider in evaluating the consumer's application. The disposal of records connected with a specific request for a medical accommodation is beyond the scope of this rule and may not be appropriate in certain circumstances.

The proposal contained examples to illustrate the medical accommodation exception. In the interim final rule, the examples have been moved to paragraph (e)(4) and revised and expanded to address commenters' concerns.

By its terms, the medical accommodation exception incorporates a non-discrimination provision, because

a creditor may only use medical information to ''accommodate'' or favor the consumer's particular circumstances. Using medical information to discriminate against or disadvantage the consumer would not meet the requirements of the exception. Nothing in this rule, however, requires a creditor to consider medical information at the consumer's request or to provide an accommodation to the consumer. Under this rule, a creditor may disregard medical information obtained in connection with a consumer's specific request for an accommodation and evaluate the consumer in accordance with the creditor's otherwise applicable underwriting criteria. Other applicable laws, including applicable fair lending laws, may require creditors to consider such requests in certain circumstances. Consideration of circumstances governed by other applicable laws is beyond the scope of this rule. The example in renumbered paragraph (e)(4)(i) has been revised to clarify the creditor's options when presented with a specific request from a consumer for a medical accommodation.

The example in renumbered paragraph (e)(4)(ii) has been revised to apply to a specific request made by telephone and documented by the creditor. The example in paragraph (e)(4)(iii) is new and illustrates how a specific request may be made by the consumer on a credit application.

A consumer who specifically requests a medical accommodation may not provide sufficient information to enable a creditor to determine whether such an accommodation is warranted. In that case, a creditor may request additional information as necessary to verify or corroborate the information provided or to enable the creditor to determine whether to make a medical accommodation for the consumer's particular circumstances. The consumer at any time may decline to provide further medical information, withdraw the request for an accommodation, and choose to be evaluated according to the creditor's otherwise applicable underwriting criteria. The example in paragraph (e)(4)(iv) is new and illustrates how creditor requests for additional information may be handled.

As noted in the proposal, creditors may not rely on the medical accommodation exception to routinely obtain and use medical information about consumers in connection with credit eligibility determinations. This exception is triggered when the consumer specifically requests an accommodation. The requirement for a specific request from the consumer is not satisfied by a creditor routinely including boilerplate language in a credit application which indicates that by applying for credit the consumer authorizes or consents to the creditor obtaining and using medical information in connection with credit eligibility determinations. The example in paragraph (e)(4)(v) is new and illustrates that routine requests by creditors do not fall within the exception.

Forbearance. In the proposal, forbearance practices and programs were addressed as an interpretation, rather than as an exception. Industry commenters believed that the proposed interpretation was too narrow because it only covered the triggering of forbearance practices and programs. These commenters believed that medical information should be available for use in determining whether to offer forbearance practices or programs to the consumer. Several industry commenters also requested clarification that informal forbearance practices would be covered by this interpretation. Privacy advocates, consumer and community groups, and health care associations suggested limiting the proposed interpretation to forbearance practices and programs triggered by a medically related event.

In the interim final rule, forbearance practices and programs are addressed in a new exception in paragraph (e)(1)(vii). Forbearance practices and programs may be established to address both medical and non-medical events. The exception, however, applies only to forbearance practices and programs that are triggered by medical events or conditions. Accordingly, paragraph (e)(1)(vii) of the interim final rule creates an exception to permit creditors to obtain and use medical information ''consistent with safe and sound practices, to determine whether the provisions of a forbearance practice or program that is triggered by a medical event or condition apply to a consumer.'' This exception is flexible enough to cover both formal and informal forbearance practices and programs. Application of a forbearance practice or program may or may not be based on the request of the consumer. Paragraph (e)(5) provides an example of a forbearance practice or program.

Debt cancellation contracts, debt suspension agreements, or credit insurance products. As noted above, the proposal addressed debt cancellation contracts, debt suspension agreements, and credit insurance products through an interpretation. Most commenters believed that it was more appropriate to address these contracts, agreements, and products through an exception. The FTC, however, recommended that the Agencies continue to address debt cancellation contracts, debt suspension agreements, and credit insurance products through an interpretation. The Agencies believe that the better approach is to create exceptions and, thus, have created two new exceptions in paragraphs (e)(1)(viii) (covering debt cancellation contracts and debt suspension agreements) and (e)(1)(ix) (covering credit insurance products) for the reasons discussed below.

Industry commenters believed that the proposed interpretation was too narrow because it only covered the triggering of debt cancellation contracts, debt suspension agreements, and credit insurance products. These commenters believed that medical information should be available for use in determining the consumer's eligibility for, the triggering of, or the reactivation of those contracts, agreements, or products. Privacy advocates, consumer and community groups, and health care associations believed that the proposed interpretation was too broad because debt cancellation contracts and debt suspension agreements are often triggered by events such as loss of employment or divorce that have no connection with medical information. Privacy advocates, consumer and community groups, and health care associations urged the Agencies to delete credit insurance from the proposed provision, maintaining that creditors typically do not offer credit insurance directly. Industry commenters had various suggestions regarding credit insurance, including creating a separate exception for credit insurance, referencing credit insurance in the preceding paragraph (a)(2)(i)(A) (now paragraph (b)(2)(iii)(A)), or broadening the proposed interpretation to cover eligibility and reactivation determinations.

In the interim final rule, debt cancellation contracts and debt suspension agreements are addressed in one exception (paragraph (e)(1)(viii)) and credit insurance products are addressed in a separate exception (paragraph (e)(1)(ix)) in recognition of the distinct character of those products. *See also* sections __.4(a)(8) and (9) of the separate rule.

Under this rule, a creditor may not use medical information about a consumer to determine whether the consumer will be required to obtain a debt cancellation contract, debt suspension agreement, or credit insurance product. For example, a consumer who is in a wheelchair cannot be required to obtain credit insurance

because of the consumer's disability. An example in paragraph (d)(2)(iii)(C) of each Agency's rule and in § __.3(b)(3)(iii) of the separate rule illustrates this limitation. Also, a creditor would not violate this particular rule if it requires all consumers who seek a particular type of credit, such as credit to finance the purchase of a home with a small down payment, to obtain credit insurance or a similar product.

The rule makes clear that creditors may use medical information to underwrite credit insurance, or to underwrite related credit products, such as debt cancellation contracts and debt suspension agreements, if a medical condition or event is a triggering event for the provision of benefits. However, denial of these products cannot be used as a subterfuge to consider medical information in making a determination about eligibility or continued eligibility for the underlying loan.

In addition, other laws and regulations, including applicable anti-tying rules and fair lending laws, may prohibit or otherwise restrict a creditor from requiring a consumer to obtain a debt cancellation contract, debt suspension agreement, or credit insurance product in connection with an extension of credit.[10] A discussion of the circumstances prohibited by other laws and regulations is beyond the scope of this rule.

Finally, creditors are reminded that when a creditor offers a consumer a debt cancellation contract, debt suspension agreement, or credit insurance product that is related to a credit product that the consumer obtains or seeks to obtain from the creditor, it may not be clear to the consumer why the creditor is seeking to obtain medical information. As discussed below, creditors generally would be prohibited from specifically asking for medical information on a credit application, except where a creditor has a specific application for the financing of medical procedures. Whether medical information is collected on the credit application or through other means, creditors should make it clear to consumers that the purpose for obtaining medical information relates to debt cancellation contracts, debt suspension agreements, or credit insurance products, rather than to the credit itself. Moreover, where obtaining those products is voluntary, the consumer should be told that it is not necessary to provide medical information and that the failure to answer medically related questions will have no impact on the credit decision.

Deleted exceptions and additional exceptions requested by commenters. Proposed paragraph (d)(1)(iii) provided that a creditor may obtain and use uncoded medical information included in a consumer report furnished by a consumer reporting agency in accordance with section 604(g)(1)(B) of the FCRA, if such information is used for the purpose for which the consumer provided specific written consent. As discussed above, this proposed exception has been eliminated.

Proposed paragraph (d)(1)(vii) provided that a creditor may obtain and use medical information as otherwise permitted by order of the appropriate agency. Privacy advocates, consumer and community groups, and health care associations objected to this provision. The Agencies believe this paragraph is unnecessary and have omitted it from the interim final rule because the Agencies are adopting identical exceptions and, as noted above, intend to make any amendments to the rules in consultation and coordination with each other.

Commenters also requested the creation of a number of additional exceptions for flexible spending programs tied to credit cards, for products tied to a consumer's life expectancy, and to facilitate resolution of direct disputes with consumers. The Agencies believe that additional exceptions are not needed and that commenters' concerns are adequately addressed by the interpretation of ''eligibility, or continued eligibility, for credit'' and the existing exceptions.

Section __.31 Limits on Redisclosure of Information

Proposed section __.30(e) incorporated the statutory provision regarding the limits on redisclosure of medical information. In the proposal, this paragraph provided that a person that receives medical information about a consumer from a consumer reporting agency or an affiliate is prohibited from disclosing that information to any other person, except as necessary to carry out the purposes for which the information was initially disclosed, or as otherwise permitted by statute, regulation, or order.

Some commenters requested clarification of the phrase ''as otherwise permitted by statute, regulation, or order'' that is used in the statute and proposed regulation. Other commenters requested clarification that a redisclosure may be made for any purpose described in section 502(e) of the GLB Act. The Agencies believe that the redisclosure language, which was taken directly from the statute, is clear and that no further clarification is necessary.

In the interim final rules, the Agencies are adopting this provision in a new section __.31 in each Agency's rule pursuant to their joint rulemaking authority under section 621(e) of the FCRA. The separate rule does not contain a similar provision on redisclosure limits.

Section __.32 Sharing Medical Information With Affiliates

Section __.31 of the proposal addressed the sharing of medically related information with affiliates. In the interim final rule, these provisions are contained in section __.32.

Proposed paragraph (a) provided that the standard exclusions from the definition of ''consumer report'' contained in section 603(d)(2) of the Act—including the exclusions for sharing transaction or experience information among affiliates or sharing other eligibility information among affiliates after notice and an opportunity to opt-out—do not apply if medical information, an individualized list or description based on payment transactions for medical products or services, or an aggregate list or description based on payment transactions for medical products or services is disclosed to an affiliate.

Proposed paragraph (b) provided that the special restrictions on sharing medically related information with affiliates did not apply, and the standard exclusions from the definition of consumer report remained in effect, if the information was disclosed to an affiliate in certain circumstances. The proposal incorporated each of the exceptions enumerated in section 604(g)(3)(A) and (B) of the Act.

The first statutory exception is when medically related information is shared with an affiliate in connection with the business of insurance or annuities (including the activities described in section 18B of the model Privacy of Consumer Financial and Health Information Regulation issued by the National Association of Insurance Commissioners (NAIC), as in effect on January 1, 2003). Some commenters questioned the adequacy of the comment period based on the fact that the NAIC model privacy regulation is

[10] For example, banks are prohibited from conditioning an extension of credit on the consumer obtaining some additional credit, property or service from the bank or its affiliate other than a loan, discount, deposit or trust service, *see* Bank Holding Company Amendments of 1970 § 106(b) (12 U.S.C. 1972); *see also* 12 CFR 37.3(a) (providing that a national bank may not extend credit nor alter the terms or conditions of an extension of credit conditioned upon the customer entering into a debt cancellation contract or debt suspension agreement with the bank).

not readily available to the public, but must be purchased from NAIC. The reference to the NAIC model privacy regulation is a statutory reference that the Agencies have incorporated into the regulation. Interested parties may purchase a copy of the NAIC model Privacy of Consumer Financial and Health Information Regulation at *http://www.naic.org*.

The second statutory exception is when medically related information is shared with an affiliate for any purpose permitted without authorization under the Standards for Individually Identifiable Health Information promulgated by the Department of Health and Human Services (HHS) pursuant to the Health Insurance Portability and Accountability Act of 1996 (HIPAA). One commenter asked the Agencies to broaden this exception by deleting the phrase ''for any purpose permitted without authorization'' and replacing it with a reference to any sharing ''as permitted under'' the HIPAA regulations issued by HHS. The Agencies find no basis for altering the specific exceptions adopted by Congress. Furthermore, the Agencies note that the special affiliate sharing restrictions do not apply unless the communication of medically related information would otherwise meet the definition of a ''consumer report.''

The third statutory exception is when medically related information is shared with an affiliate for any purpose referred to under section 1179 of HIPAA. Section 1179 of HIPAA provides that to the extent that an entity is engaged in activities of a financial institution or is engaged in authorizing, processing, clearing, settling, billing, transferring, reconciling or collecting payments for a financial institution, the HIPAA standards and requirements do not apply to the entity with respect to such activities. Section 1179 also provides as an example of a use or disclosure of information not covered by that statute, the use or disclosure of information for authorizing, processing, clearing, settling, billing, transferring, reconciling, or collection, a payment for, or related to, health care premiums or health care. Some commenters requested that the Agencies contact the Department of Health and Human Services (HHS) to clarify an issue regarding the scope of section 1179. Any consultation with HHS regarding section 1179 of HIPAA would be independent of this rulemaking.

The fourth statutory exception is when medically related information is shared with an affiliate for any purpose described in section 502(e) of the GLB Act. As previously noted in the proposal, some of the purposes described in section 502(e) of the GLB Act may be germane to the sharing of information among affiliates—for example, sharing with the consent of the consumer, for fraud prevention purposes, or as necessary to effect, administer, or enforce a transaction requested or authorized by the consumer—while other purposes described in section 502(e) are not—for example, sharing information with law enforcement or regulatory authorities.

The fifth exception is not set forth in the statute and provides that the special restrictions on sharing medically related information with affiliates do not apply, and the standard exclusions from the definition of consumer report remain in effect, if the information is disclosed to an affiliate in connection with a determination of the consumer's eligibility, or continued eligibility, for credit consistent with § __.30 of this subpart. Industry commenters supported this exception. Privacy advocates, consumer and community groups, and health care associations requested the deletion of this exception or, as an alternative, that this exception not apply to uncoded medical information obtained from a consumer reporting agency with the consumer's specific written consent or to information obtained pursuant to the medical accommodation exception. This exception is adopted as proposed in paragraph (b)(5).

The Agencies continue to believe that it is necessary and appropriate to allow a person to share medically related information with an affiliate in connection with a determination of the consumer's eligibility, or continued eligibility, for credit consistent with the provisions of § __.30. In response to commenters' concerns, the Agencies note that the interim final rule permits uncoded medical information from a consumer reporting agency to be used only as permitted by the exceptions in § __.30(d) and (e). Moreover, the medical accommodation exception restricts creditors from routinely obtaining and using medical information because the exception is triggered by a consumer's specific request. Thus, the Agencies believe that the provisions of § __.30(d) and (e) are sufficient to prevent the inappropriate sharing of medical information with and the inappropriate use of medical information by affiliates.

Finally, the sixth exception provides that the special restrictions on sharing medically related information with affiliates would not apply if otherwise permitted by order of the appropriate agency. This exception incorporates the authority delegated to the Agencies by the Congress to create exceptions through orders. Privacy advocates, consumer and community groups, and health care associations acknowledged the authority of the Agencies to expand the affiliate-sharing exceptions by order. This exception is adopted as proposed in paragraph (b)(6).

As noted in the proposal, the prohibitions on obtaining or using medical information in § __.30 operate independently from the exceptions that permit the sharing of that information among affiliates in accordance with the provisions of section 603(d)(2) of the Act. For example, if a mortgage lender has obtained and used medical information in accordance with one of the exceptions in § __.30(c) or (d), the mortgage lender may share that information with its credit card affiliate without becoming a consumer reporting agency if one of the exceptions in § __.32(b) applies. However, the credit card affiliate may not obtain or use that information in connection with any determination of the consumer's eligibility, or continued eligibility, for credit, except to the extent permitted by § __.30.

Effective Date and Solicitation of Comments

The statute provides that the final rules shall take effect on the later of 90 days after the rules are issued in final form, or the date specified in the regulations. Commenters believed that the effective date of the final rules should be no sooner than 90 days after the rules are issued in final form, although many commenters requested a longer period before the final rules take effect. Commenters generally believed that the effective date should be synchronized with the statutory prohibition, so that creditors would not be subject to the prohibition on obtaining or using medical information before the effective date of the regulatory exceptions. The interim final rules shall take effect on March 7, 2006, which is 270 days after the date of publication in the **Federal Register**. Comments on the interim final rule must be received by July 11, 2005.

V. Regulatory Analysis

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3506, *et seq.*) and its implementing regulations at 5 CFR part 1320, including Appendix A.1, the Agencies have reviewed the interim final rules and determined that they contain no collections of information. The Board

made this determination under authority delegated by the Office of Management and Budget.

Regulatory Flexibility Analysis

OCC: The OCC received no comment on its Initial Regulatory Flexibility Analysis published in connection with the April 28, 2004, NPRM. Upon further review, the OCC certifies that this interim final rule will not have a significant economic impact on a substantial number of small entities.

Under section 605(b) of the Regulatory Flexibility Act (RFA), 5 U.S.C. 605(b), the regulatory flexibility analysis otherwise required under section 604 of the RFA is not required if an agency certifies, along with a statement providing the factual basis for such certification, that the rule will not have a significant economic impact on a substantial number of small entities. The OCC has reviewed the impact of this interim final rule on small entities and certifies that it will not have a significant economic impact on a substantial number of small entities.

The Small Business Administration (SBA) has defined ''small entities'' for banking purposes as a bank or savings institution with assets of $150 million or less. *See* 13 CFR 121.201. The interim final rule implements section 411 of the FACT Act and imposes only minimal economic impact on national banks. The interim final rule creates exceptions to the FACT Act's prohibition against national banks obtaining and using a consumer's medical information in connection with credit determinations. Additionally, the interim final rule implements the FACT Act's restrictions on the sharing of medical information among affiliates and includes exceptions to permit the sharing of medical information in certain circumstances. The interim final rule applies to national banks, Federal branches and agencies, their respective subsidiaries, and persons that participate in a credit transaction involving a national bank, Federal Branch or agency, or their respective subsidiaries (''entities'') that obtain or use medical information in connection with credit determinations, regardless of their size. However, it is likely that small entities, because of the nature and size of their operations, will encounter fewer instances where they might obtain or use medical information. Therefore, the interim final rule is not expected to result in a significant economic impact for small national entities.

Board: The Board has prepared a final regulatory flexibility analysis as required by the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*).

1. *Statement of the need for and objectives of the interim final rule.* The FACT Act amends the FCRA and was enacted, in part, for the purpose of protecting consumers' medical information. Section 411 of the FACT Act contains a general prohibition on creditors obtaining or using medical information pertaining to a consumer in connection with any determination of the consumer's eligibility, or continued eligibility, for credit. Section 411 authorizes the Board, together with the other Agencies, to create exceptions to allow creditors to obtain or use medical information for eligibility purposes where necessary and appropriate to protect legitimate operational, transactional risk, consumer, and other needs, consistent with the Congressional intent to restrict the use of medical information for inappropriate purposes.

Section 411 also limits the ability of an institution to share medical information with its affiliates without becoming a consumer reporting agency, subject to certain exceptions, and restricts the redisclosure of medical information. The statute authorizes the Board to issue regulations to create additional exceptions that are determined to be necessary and appropriate to permit the sharing of medical information among affiliates. The Board is adopting the interim final rule to create exceptions that permit creditors to obtain and use medical information in credit eligibility determinations, restate the limits on redisclosure, and restate and add to the exceptions that allow sharing among affiliates. The **SUPPLEMENTARY INFORMATION** above contains information on the objectives of the interim final rule.

2. *Summary of issues raised by comments in response to the initial regulatory flexibility analysis.* In accordance with section 3(a) of the Regulatory Flexibility Act, the Board conducted an initial regulatory flexibility analysis in connection with the proposed rule. The Board did not receive any comments on its initial regulatory flexibility analysis.

3. *Description of small entities affected by the proposal.* Each section of the interim final rule applies to different types of small entities and specifies the types of small entities subject to that section. The interim final rule would apply, in whole or in part, to banks that are members of the Federal Reserve System (other than national banks) and their subsidiaries, branches and Agencies of foreign banks (other than Federal branches, Federal Agencies, and insured State branches of foreign banks) and their subsidiaries, commercial lending companies owned or controlled by foreign banks, organizations operating under section 25 or 25A of the Federal Reserve Act (12 U.S.C. 601 *et seq.*, and 611 *et seq.*), bank holding companies and affiliates of such holding companies (other than depository institutions and consumer reporting agencies), and creditors that participate in a transaction with one of the above-mentioned entities. A separate rule would apply to creditors not otherwise subject to one of the Agency rules. The Board's interim final rule will apply to the following institutions (numbers approximate): State member banks (932), bank holding companies (5,152), holding company non-bank subsidiaries (2,131), U.S. branches and agencies of foreign banks (289), and Edge and agreement corporations (75), for a subtotal of approximately 8,579 institutions. The Board estimates that over 5,000 of these institutions could be considered small institutions with assets less than $150 million. The Board is unable to estimate the number of creditors that may participate in transactions with such institutions or the number of other creditors that may be covered by the separate rule.

All small entities that are creditors will be affected by the provision of the interim final rule that addresses the prohibition on, and exceptions to, creditors obtaining or using medical information in connection with credit eligibility determinations. All small creditors will have to comply with the exceptions if they obtain or use medical information about consumers in connection with any credit eligibility determination.

4. *Recordkeeping, reporting, and compliance requirements.* The interim final rule requires certain documentation to qualify for some of the specific exceptions, as discussed in the **SUPPLEMENTARY INFORMATION** above. The interim final rule contains no reporting or disclosure requirements.

5. *Steps taken to minimize the economic impact on small entities.* The Board solicited comment on how to minimize the economic impact on small entities. The Board did not receive any comments on this issue. By adopting consistent rules and exceptions, the Board and the other Agencies have attempted to minimize the economic impact on small entities.

FDIC: The Agencies received no comments on their initial regulatory flexibility analyses. Upon further analysis, the FDIC certifies that this rule creating exceptions to the FACT Act's general prohibition on creditors obtaining or using medical information

pertaining to a consumer in connection with any determination of the consumer's eligibility, or continued eligibility, for credit will not have a significant economic impact on small entities. This interim final rule, as authorized by section 411 of the FACT Act, creates exceptions to allow creditors to obtain or use medical information for eligibility purposes where necessary and appropriate to protect legitimate operational, transactional risk, consumer, and other needs, consistent with the Congressional intent to restrict the use of medical information for inappropriate purposes. The rule also excludes, in certain situations, medical information shared by a covered entity with an affiliate from the definition of a consumer report in section 603(d) of the FCRA, and addresses the reuse and redisclosure of medical information.

OTS: In accordance with section 603(a) of the Regulatory Flexibility Act (RFA) (5 U.S.C. 603(a)), OTS conducted an initial regulatory flexibility analysis in connection with the April 28, 2004 proposed rule. OTS did not receive any comments on its initial regulatory flexibility analysis.

Upon further analysis, OTS certifies in accordance with section 605(b) of the RFA (5 U.S.C. 605(b)) that this interim final rule will not have a significant economic impact on a substantial number of small entities. The Small Business Administration (SBA) has generally defined small savings institutions for RFA purposes as those with assets of $150 million or less. 13 CFR 121.201.

This interim final rule implements section 411 of the FACT Act and imposes only minimal economic impact. Section 571.30 creates exceptions to allow creditors to obtain or use medical information for credit eligibility purposes where necessary and appropriate to protect legitimate operational, transactional risk, consumer, and other needs, consistent with the congressional intent to restrict the use of medical information for inappropriate purposes. It applies to all any of the following, regardless of size, that participates as a creditor in a transaction: (1) A savings association; (2) a subsidiary owned in whole or in part by a savings association; (3) a savings and loan holding company; (4) a subsidiary of a savings and loan holding company other than a bank or subsidiary of a bank; (5) a service corporation owned in whole or in part by a savings association; or (6) any other person that participates as a creditor in a transaction involving a person described (1)–(5).

Section 571.31 implements the FACT Act's restrictions on the redisclosure of information. Section 571.32 implements the FACT Act's restrictions on the sharing of medical information among affiliates and includes exceptions to permit the sharing of medical information in certain circumstances. These sections apply to savings associations and Federal savings association operating subsidiaries, regardless of size.

As referenced elsewhere in this **SUPPLEMENTARY INFORMATION,** other laws and regulations, such as the Fair Housing Act, the Americans with Disabilities Act, and OTS's anti-discrimination rules in 12 CFR part 528, also limit or regulate obtaining and using medical information for credit eligibility determinations in a manner that discriminates against persons whose medical condition constitutes a ''disability'' or ''handicap'' under those authorities. Other laws, such as the GLB Act, HIPAA, and other parts of the FCRA, also limit or regulate the use, collection, and sharing of consumer information, including medical information. The industry's preexisting familiarity and compliance with the requirements of these other authorities to the extent applicable is one factor that OTS expects will minimize the economic impact of today's interim final rule.

NCUA: The Regulatory Flexibility Act requires NCUA to prepare an analysis to describe any significant economic impact any regulation may have on a substantial number of small entities. NCUA considers credit unions having less than ten million dollars in assets to be small for purposes of the Regulatory Flexibility Act. NCUA Interpretive Ruling and Policy Statement (IRPS) 87–2, as amended by IRPS 03–2. NCUA conducted an initial regulatory flexibility analysis in connection with the proposed rule and did not receive any comments on it.

Upon further review, NCUA certifies that this interim final rule will not have a significant economic impact on a substantial number of small entities. The interim final rule applies to all Federal credit unions that obtain or use a consumer's medical information in connection with credit determinations, regardless of credit union size. The interim final rule creates exceptions to the FACT Act's prohibition against Federal credit unions obtaining and using such information in connection with credit determinations. Additionally, the interim final rule implements the FACT Act's restrictions on the sharing of medical information among Federal credit union affiliates, credit union service organizations (CUSOs), and includes exceptions to permit the sharing of medical information in certain circumstances.

FDIC—Small Business Regulatory Enforcement Act

The Small Business Regulatory Enforcement Act of 1996 (SBREFA) (Pub. L. 104–121, 110 Stat. 857) provides generally for agencies to report rules to Congress and for Congress to review these rules. The reporting requirement is triggered in instances where the FDIC issues a final rule as defined by the Administrative Procedure Act (APA) (5 U.S.C. 55, *et seq.*). Because the FDIC is issuing a final rule as defined by the APA, the FDIC will file the reports required by SBREFA.

OCC and OTS Executive Order 12866 Determination

The OCC and OTS each has determined that its portion of the rule is not a significant regulatory action under Executive Order 12866.

OCC Executive Order 13132 Determination

The OCC has determined that this rule does not have any Federalism implications, as required by Executive Order 13132.

NCUA Executive Order 13132 Determination

Executive Order 13132 encourages independent regulatory agencies to consider the impact of their actions on state and local interests. In adherence to fundamental federalism principles, the NCUA, an independent regulatory agency as defined in 44 U.S.C. 3502(5), voluntarily complies with the executive order. The rule applies only to federally chartered credit unions and would not have substantial direct effects on the states, on the connection between the national government and the states, or on the distribution of power and responsibilities among the various levels of government. The NCUA has determined that this rule does not constitute a policy that has federalism implications for purposes of the executive order.

OCC and OTS Unfunded Mandates Reform Act of 1995 Determination

Section 202 of the Unfunded Mandates Reform Act of 1995, Public Law 104–4 (Unfunded Mandates Act) requires that an agency prepare a budgetary impact statement before promulgating a rule that includes a Federal mandate that may result in expenditure by State, local, and tribal

governments, in the aggregate, or by the private sector, of $100 million or more in any one year. If a budgetary impact statement is required, section 205 of the Unfunded Mandates Act also requires an agency to identify and consider a reasonable number of regulatory alternatives before promulgating a rule. The OCC and OTS each has determined that this rule will not result in expenditures by State, local, and tribal governments, or by the private sector, of $100 million or more. Accordingly, neither the OCC nor the OTS has prepared a budgetary impact statement or specifically addressed the regulatory alternatives considered.

NCUA: The Treasury and General Government Appropriations Act, 1999—Assessment of Federal Regulations and Policies on Families

The NCUA has determined that this rule would not affect family well-being within the meaning of section 654 of the Treasury and General Government Appropriations Act, 1999, Pub. L. 105–277, 112 Stat. 2681 (1998).

Plain Language Requirement

Section 722 of the Gramm-Leach-Bliley Act (GLBA) (12 U.S.C. 4809), requires the Federal banking agencies to use plain language in all proposed and final rules published after January 1, 2000. The proposed rule requested comments on how the rule might be changed to reflect the requirements of GLBA. No GLBA comments were received.

List of Subjects

12 CFR Part 41

Banks, banking, Consumer protection, National banks, Reporting and recordkeeping requirements.

12 CFR Part 222

Banks, banking, Consumer protection, Credit, Fair Credit Reporting Act, Holding companies, Privacy, Reporting and recordkeeping requirements, State member banks.

12 CFR Part 232

Consumer protection, Credit, Fair Credit Reporting Act, Privacy, Reporting and recordkeeping requirements.

12 CFR Part 334

Administrative practice and procedure, Bank deposit insurance, Banks, banking, Reporting and recordkeeping requirements, Safety and soundness.

12 CFR Part 571

Consumer protection, Credit, Fair Credit Reporting Act, Privacy, Reporting and recordkeeping requirements, Savings associations.

12 CFR Part 717

Consumer protection, Credit unions, Fair credit reporting, Medical information, Privacy, Reporting and recordkeeping requirements.

Office of the Comptroller of the Currency

12 CFR Chapter I.

Authority and Issuance

■ For the reasons set forth in the preamble, the OCC amends Chapter I of Title 12 of the Code of Federal Regulations as follows:

PART 41—FAIR CREDIT

■ 1. Revise the authority citation for part 41 to read as follows:

Authority: 12 U.S.C. 1 *et seq.*, 24(Seventh), 93a, 481, 484, and 1818; 15 U.S.C. 1681a, 1681b, 1681s, 1681w, 6801, and 6805.

■ 2. Revise subpart A to read as follows:

Subpart A—General Provisions

§ 41.2 Examples.

The examples in this part are not exclusive. Compliance with an example, to the extent applicable, constitutes compliance with this part. Examples in a paragraph illustrate only the issue described in the paragraph and do not illustrate any other issue that may arise in this part.

§ 41.3 Definitions.

As used in this part, unless the context requires otherwise:

(a) *Act* means the Fair Credit Reporting Act (15 U.S.C. 1681 *et seq.*).

(b) *Affiliate* means any company that is related by common ownership or common corporate control with another company.

(c) [Reserved]

(d) *Company* means any corporation, limited liability company, business trust, general or limited partnership, association, or similar organization.

(e) *Consumer* means an individual.

(f) [Reserved]

(g) [Reserved]

(h) [Reserved]

(i) *Common ownership or common corporate control* means a relationship between two companies under which:

(1) One company has, with respect to the other company:

(i) Ownership, control, or power to vote 25 percent or more of the outstanding shares of any class of voting security of a company, directly or indirectly, or acting through one or more other persons;

(ii) Control in any manner over the election of a majority of the directors, trustees, or general partners (or individuals exercising similar functions) of a company; or

(iii) The power to exercise, directly or indirectly, a controlling influence over the management or policies of a company, as the OCC determines; or

(2) Any other person has, with respect to both companies, a relationship described in paragraphs (i)(1)(i)-(i)(1)(iii) of this section.

(j) [Reserved]

(k) *Medical information* means:

(1) Information or data, whether oral or recorded, in any form or medium, created by or derived from a health care provider or the consumer, that relates to—

(i) The past, present, or future physical, mental, or behavioral health or condition of an individual;

(ii) The provision of health care to an individual; or

(iii) The payment for the provision of health care to an individual.

(2) The term does not include:

(i) The age or gender of a consumer;

(ii) Demographic information about the consumer, including a consumer's residence address or e-mail address;

(iii) Any other information about a consumer that does not relate to the physical, mental, or behavioral health or condition of a consumer, including the existence or value of any insurance policy; or

(iv) Information that does not identify a specific consumer.

(l) *Person* means any individual, partnership, corporation, trust, estate cooperative, association, government or governmental subdivision or agency, or other entity.

■ 3. Add subpart D to read as follows:

Subpart D—Medical Information

§ 41.30 Obtaining or using medical information in connection with a determination of eligibility for credit.

(a) *Scope.* This section applies to:

(1) Any person that participates as a creditor in a transaction and that is a national bank, a Federal branch or agency of a foreign bank, and their respective subsidiaries; or

(2) Any other person that participates as a creditor in a transaction involving a person described in paragraph (a)(1) of this section.

(b) *General prohibition on obtaining or using medical information.* (1) *In general.* A creditor may not obtain or use medical information pertaining to a consumer in connection with any determination of the consumer's eligibility, or continued eligibility, for

credit, except as provided in this section.

(2) *Definitions.* (i) *Credit* has the same meaning as in section 702 of the Equal Credit Opportunity Act, 15 U.S.C. 1691a.

(ii) *Creditor* has the same meaning as in section 702 of the Equal Credit Opportunity Act, 15 U.S.C. 1691a.

(iii) *Eligibility, or continued eligibility, for credit* means the consumer's qualification or fitness to receive, or continue to receive, credit, including the terms on which credit is offered. The term does not include:

(A) Any determination of the consumer's qualification or fitness for employment, insurance (other than a credit insurance product), or other non-credit products or services;

(B) Authorizing, processing, or documenting a payment or transaction on behalf of the consumer in a manner that does not involve a determination of the consumer's eligibility, or continued eligibility, for credit; or

(C) Maintaining or servicing the consumer's account in a manner that does not involve a determination of the consumer's eligibility, or continued eligibility, for credit.

(c) *Rule of construction for obtaining and using unsolicited medical information.* (1) *In general.* A creditor does not obtain medical information in violation of the prohibition if it receives medical information pertaining to a consumer in connection with any determination of the consumer's eligibility, or continued eligibility, for credit without specifically requesting medical information.

(2) *Use of unsolicited medical information.* A creditor that receives unsolicited medical information in the manner described in paragraph (c)(1) of this section may use that information in connection with any determination of the consumer's eligibility, or continued eligibility, for credit to the extent the creditor can rely on at least one of the exceptions in § 41.30(d) or (e).

(3) *Examples.* A creditor does not obtain medical information in violation of the prohibition if, for example:

(i) In response to a general question regarding a consumer's debts or expenses, the creditor receives information that the consumer owes a debt to a hospital.

(ii) In a conversation with the creditor's loan officer, the consumer informs the creditor that the consumer has a particular medical condition.

(iii) In connection with a consumer's application for an extension of credit, the creditor requests a consumer report from a consumer reporting agency and receives medical information in the consumer report furnished by the agency even though the creditor did not specifically request medical information from the consumer reporting agency.

(d) *Financial information exception for obtaining and using medical information.* (1) *In general.* A creditor may obtain and use medical information pertaining to a consumer in connection with any determination of the consumer's eligibility, or continued eligibility, for credit so long as:

(i) The information is the type of information routinely used in making credit eligibility determinations, such as information relating to debts, expenses, income, benefits, assets, collateral, or the purpose of the loan, including the use of proceeds;

(ii) The creditor uses the medical information in a manner and to an extent that is no less favorable than it would use comparable information that is not medical information in a credit transaction; and

(iii) The creditor does not take the consumer's physical, mental, or behavioral health, condition or history, type of treatment, or prognosis into account as part of any such determination.

(2) *Examples.* (i) *Examples of the types of information routinely used in making credit eligibility determinations.* Paragraph (d)(1)(i) of this section permits a creditor, for example, to obtain and use information about:

(A) The dollar amount, repayment terms, repayment history, and similar information regarding medical debts to calculate, measure, or verify the repayment ability of the consumer, the use of proceeds, or the terms for granting credit;

(B) The value, condition, and lien status of a medical device that may serve as collateral to secure a loan;

(C) The dollar amount and continued eligibility for disability income or benefits related to health or a medical condition that is relied on as a source of repayment; or

(D) The identity of creditors to whom outstanding medical debts are owed in connection with an application for credit, including but not limited to, a transaction involving the consolidation of medical debts.

(ii) *Examples of uses of medical information consistent with the exception.* (A) A consumer includes on an application for credit information about two $20,000 debts. One debt is to a hospital; the other debt is to a retailer. The creditor contacts the hospital and the retailer to verify the amount and payment status of the debts. The creditor learns that both debts are more than 90 days past due. Any two debts of this size that are more than 90 days past due would disqualify the consumer under the creditor's established underwriting criteria. The creditor denies the application on the basis that the consumer has a poor repayment history on outstanding debts. The creditor has used medical information in a manner and to an extent no less favorable than it would use comparable non-medical information.

(B) A consumer indicates on an application for a $200,000 mortgage loan that she receives $15,000 in long-term disability income each year from her former employer and has no other income. Annual income of $15,000, regardless of source, would not be sufficient to support the requested amount of credit. The creditor denies the application on the basis that the projected debt-to-income ratio of the consumer does not meet the creditor's underwriting criteria. The creditor has used medical information in a manner and to an extent that is no less favorable than it would use comparable non-medical information.

(C) A consumer includes on an application for a $10,000 home equity loan that he has a $50,000 debt to a medical facility that specializes in treating a potentially terminal disease. The creditor contacts the medical facility to verify the debt and obtain the repayment history and current status of the loan. The creditor learns that the debt is current. The applicant meets the income and other requirements of the creditor's underwriting guidelines. The creditor grants the application. The creditor has used medical information in accordance with the exception.

(iii) *Examples of uses of medical information inconsistent with the exception.* (A) A consumer applies for $25,000 of credit and includes on the application information about a $50,000 debt to a hospital. The creditor contacts the hospital to verify the amount and payment status of the debt, and learns that the debt is current and that the consumer has no delinquencies in her repayment history. If the existing debt were instead owed to a retail department store, the creditor would approve the application and extend credit based on the amount and repayment history of the outstanding debt. The creditor, however, denies the application because the consumer is indebted to a hospital. The creditor has used medical information, here the identity of the medical creditor, in a manner and to an extent that is less favorable than it would use comparable non-medical information.

(B) A consumer meets with a loan officer of a creditor to apply for a

mortgage loan. While filling out the loan application, the consumer informs the loan officer orally that she has a potentially terminal disease. The consumer meets the creditor's established requirements for the requested mortgage loan. The loan officer recommends to the credit committee that the consumer be denied credit because the consumer has that disease. The credit committee follows the loan officer's recommendation and denies the application because the consumer has a potentially terminal disease. The creditor has used medical information in a manner inconsistent with the exception by taking into account the consumer's physical, mental, or behavioral health, condition, or history, type of treatment, or prognosis as part of a determination of eligibility or continued eligibility for credit.

(C) A consumer who has an apparent medical condition, such as a consumer who uses a wheelchair or an oxygen tank, meets with a loan officer to apply for a home equity loan. The consumer meets the creditor's established requirements for the requested home equity loan and the creditor typically does not require consumers to obtain a debt cancellation contract, debt suspension agreement, or credit insurance product in connection with such loans. However, based on the consumer's apparent medical condition, the loan officer recommends to the credit committee that credit be extended to the consumer only if the consumer obtains a debt cancellation contract, debt suspension agreement, or credit insurance product. The credit committee agrees with the loan officer's recommendation. The loan officer informs the consumer that the consumer must obtain a debt cancellation contract, debt suspension agreement, or credit insurance product to qualify for the loan. The consumer obtains one of these products from a third party and the creditor approves the loan. The creditor has used medical information in a manner inconsistent with the exception by taking into account the consumer's physical, mental, or behavioral health, condition, or history, type of treatment, or prognosis in setting conditions on the consumer's eligibility for credit.

(e) *Specific exceptions for obtaining and using medical information.* (1) *In general.* A creditor may obtain and use medical information pertaining to a consumer in connection with any determination of the consumer's eligibility, or continued eligibility, for credit—

(i) To determine whether the use of a power of attorney or legal representative that is triggered by a medical event or condition is necessary and appropriate or whether the consumer has the legal capacity to contract when a person seeks to exercise a power of attorney or act as legal representative for a consumer based on an asserted medical event or condition;

(ii) To comply with applicable requirements of local, State, or Federal laws;

(iii) To determine, at the consumer's request, whether the consumer qualifies for a legally permissible special credit program or credit-related assistance program that is—

(A) Designed to meet the special needs of consumers with medical conditions; and

(B) Established and administered pursuant to a written plan that—

(*1*) Identifies the class of persons that the program is designed to benefit; and

(*2*) Sets forth the procedures and standards for extending credit or providing other credit-related assistance under the program.

(iv) To the extent necessary for purposes of fraud prevention or detection;

(v) In the case of credit for the purpose of financing medical products or services, to determine and verify the medical purpose of a loan and the use of proceeds;

(vi) Consistent with safe and sound practices, if the consumer or the consumer's legal representative specifically requests that the creditor use medical information in determining the consumer's eligibility, or continued eligibility, for credit, to accommodate the consumer's particular circumstances, and such request is documented by the creditor;

(vii) Consistent with safe and sound practices, to determine whether the provisions of a forbearance practice or program that is triggered by a medical event or condition apply to a consumer;

(viii) To determine the consumer's eligibility for, the triggering of, or the reactivation of a debt cancellation contract or debt suspension agreement if a medical condition or event is a triggering event for the provision of benefits under the contract or agreement; or

(ix) To determine the consumer's eligibility for, the triggering of, or the reactivation of a credit insurance product if a medical condition or event is a triggering event for the provision of benefits under the product.

(2) *Example of determining eligibility for a special credit program or credit assistance program.* A not-for-profit organization establishes a credit assistance program pursuant to a written plan that is designed to assist disabled veterans in purchasing homes by subsidizing the down payment for the home purchase mortgage loans of qualifying veterans. The organization works through mortgage lenders and requires mortgage lenders to obtain medical information about the disability of any consumer that seeks to qualify for the program, use that information to verify the consumer's eligibility for the program, and forward that information to the organization. A consumer who is a veteran applies to a creditor for a home purchase mortgage loan. The creditor informs the consumer about the credit assistance program for disabled veterans and the consumer seeks to qualify for the program. Assuming that the program complies with all applicable law, including applicable fair lending laws, the creditor may obtain and use medical information about the medical condition and disability, if any, of the consumer to determine whether the consumer qualifies for the credit assistance program.

(3) *Examples of verifying the medical purpose of the loan or the use of proceeds.* (i) If a consumer applies for $10,000 of credit for the purpose of financing vision correction surgery, the creditor may verify with the surgeon that the procedure will be performed. If the surgeon reports that surgery will not be performed on the consumer, the creditor may use that medical information to deny the consumer's application for credit, because the loan would not be used for the stated purpose.

(ii) If a consumer applies for $10,000 of credit for the purpose of financing cosmetic surgery, the creditor may confirm the cost of the procedure with the surgeon. If the surgeon reports that the cost of the procedure is $5,000, the creditor may use that medical information to offer the consumer only $5,000 of credit.

(iii) A creditor has an established medical loan program for financing particular elective surgical procedures. The creditor receives a loan application from a consumer requesting $10,000 of credit under the established loan program for an elective surgical procedure. The consumer indicates on the application that the purpose of the loan is to finance an elective surgical procedure not eligible for funding under the guidelines of the established loan program. The creditor may deny the consumer's application because the purpose of the loan is not for a particular procedure funded by the established loan program.

(4) *Examples of obtaining and using medical information at the request of*

the consumer. (i) If a consumer applies for a loan and specifically requests that the creditor consider the consumer's medical disability at the relevant time as an explanation for adverse payment history information in his credit report, the creditor may consider such medical information in evaluating the consumer's willingness and ability to repay the requested loan to accommodate the consumer's particular circumstances, consistent with safe and sound practices. The creditor may also decline to consider such medical information to accommodate the consumer, but may evaluate the consumer's application in accordance with its otherwise applicable underwriting criteria. The creditor may not deny the consumer's application or otherwise treat the consumer less favorably because the consumer specifically requested a medical accommodation, if the creditor would have extended the credit or treated the consumer more favorably under the creditor's otherwise applicable underwriting criteria.

(ii) If a consumer applies for a loan by telephone and explains that his income has been and will continue to be interrupted on account of a medical condition and that he expects to repay the loan by liquidating assets, the creditor may, but is not required to, evaluate the application using the sale of assets as the primary source of repayment, consistent with safe and sound practices, provided that the creditor documents the consumer's request by recording the oral conversation or making a notation of the request in the consumer's file.

(iii) If a consumer applies for a loan and the application form provides a space where the consumer may provide any other information or special circumstances, whether medical or non-medical, that the consumer would like the creditor to consider in evaluating the consumer's application, the creditor may use medical information provided by the consumer in that space on that application to accommodate the consumer's application for credit, consistent with safe and sound practices, or may disregard that information.

(iv) If a consumer specifically requests that the creditor use medical information in determining the consumer's eligibility, or continued eligibility, for credit and provides the creditor with medical information for that purpose, and the creditor determines that it needs additional information regarding the consumer's circumstances, the creditor may request, obtain, and use additional medical information about the consumer as necessary to verify the information provided by the consumer or to determine whether to make an accommodation for the consumer. The consumer may decline to provide additional information, withdraw the request for an accommodation, and have the application considered under the creditor's otherwise applicable underwriting criteria.

(v) If a consumer completes and signs a credit application that is not for medical purpose credit and the application contains boilerplate language that routinely requests medical information from the consumer or that indicates that by applying for credit the consumer authorizes or consents to the creditor obtaining and using medical information in connection with a determination of the consumer's eligibility, or continued eligibility, for credit, the consumer has not specifically requested that the creditor obtain and use medical information to accommodate the consumer's particular circumstances.

(5) *Example of a forbearance practice or program.* After an appropriate safety and soundness review, a creditor institutes a program that allows consumers who are or will be hospitalized to defer payments as needed for up to three months, without penalty, if the credit account has been open for more than one year and has not previously been in default, and the consumer provides confirming documentation at an appropriate time. A consumer is hospitalized and does not pay her bill for a particular month. This consumer has had a credit account with the creditor for more than one year and has not previously been in default. The creditor attempts to contact the consumer and speaks with the consumer's adult child, who is not the consumer's legal representative. The adult child informs the creditor that the consumer is hospitalized and is unable to pay the bill at that time. The creditor defers payments for up to three months, without penalty, for the hospitalized consumer and sends the consumer a letter confirming this practice and the date on which the next payment will be due.

§ 41.31 Limits on redisclosure of information.

(a) *Scope.* This section applies to national banks, Federal branches and agencies of foreign banks, and their respective operating subsidiaries.

(b) *Limits on redisclosure.* If a person described in paragraph (a) of this section receives medical information about a consumer from a consumer reporting agency or its affiliate, the person must not disclose that information to any other person, except as necessary to carry out the purpose for which the information was initially disclosed, or as otherwise permitted by statute, regulation, or order.

§ 41.32 Sharing medical information with affiliates.

(a) *Scope.* This section applies to national banks, Federal branches and agencies of foreign banks, and their respective operating subsidiaries.

(b) *In general.* The exclusions from the term ''consumer report'' in section 603(d)(2) of the Act that allow the sharing of information with affiliates do not apply if a person described in paragraph (a) of this section communicates to an affiliate—

(1) Medical information;

(2) An individualized list or description based on the payment transactions of the consumer for medical products or services; or

(3) An aggregate list of identified consumers based on payment transactions for medical products or services.

(c) *Exceptions.* A person described in paragraph (a) may rely on the exclusions from the term ''consumer report'' in section 603(d)(2) of the Act to communicate the information in paragraph (b) to an affiliate—

(1) In connection with the business of insurance or annuities (including the activities described in section 18B of the model Privacy of Consumer Financial and Health Information Regulation issued by the National Association of Insurance Commissioners, as in effect on January 1, 2003);

(2) For any purpose permitted without authorization under the regulations promulgated by the Department of Health and Human Services pursuant to the Health Insurance Portability and Accountability Act of 1996 (HIPAA);

(3) For any purpose referred to in section 1179 of HIPAA;

(4) For any purpose described in section 502(e) of the Gramm-Leach-Bliley Act;

(5) In connection with a determination of the consumer's eligibility, or continued eligibility, for credit consistent with § 41.30; or

(6) As otherwise permitted by order of the OCC.

Board of Governors of the Federal Reserve System

12 CFR Chapter II.

Authority and Issuance

■ For the reasons set forth in the joint preamble, title 12, chapter II, of the Code

of Federal Regulations is amended as follows:

PART 222—FAIR CREDIT REPORTING (REGULATION V)

■ 1. The authority citation for part 222 is revised to read as follows:

Authority: 15 U.S.C. 1681b and 1681s; Secs. 3, 214, and 217, Pub. L. 108–159, 117 Stat. 1952.

Subpart A—General Provisions

■ 2. Amend subpart A to part 222 by adding §§222.2 and 222.3 to read as follows:

§ 222.2 Examples.

The examples in this part are not exclusive. Compliance with an example, to the extent applicable, constitutes compliance with this part. Examples in a paragraph illustrate only the issue described in the paragraph and do not illustrate any other issue that may arise in this part.

§ 222.3 Definitions.

As used in this part, unless the context requires otherwise:

(a) *Act* means the Fair Credit Reporting Act (15 U.S.C. 1681 *et seq.*).

(b) *Affiliate* means any company that is related by common ownership or common corporate control with another company.

(c) [Reserved]

(d) *Company* means any corporation, limited liability company, business trust, general or limited partnership, association, or similar organization.

(e) *Consumer* means an individual.

(f) [Reserved]

(g) [Reserved]

(h) [Reserved]

(i) *Common ownership or common corporate control* means a relationship between two companies under which:

(1) One company has, with respect to the other company:

(i) Ownership, control, or power to vote 25 percent or more of the outstanding shares of any class of voting security of a company, directly or indirectly, or acting through one or more other persons;

(ii) Control in any manner over the election of a majority of the directors, trustees, or general partners (or individuals exercising similar functions) of a company; or

(iii) The power to exercise, directly or indirectly, a controlling influence over the management or policies of a company, as the Board determines; or

(2) Any other person has, with respect to both companies, a relationship described in paragraphs (i)(1)(i)–(i)(1)(iii) of this section.

(j) [Reserved]

(k) *Medical information* means:

(1) Information or data, whether oral or recorded, in any form or medium, created by or derived from a health care provider or the consumer, that relates to—

(i) The past, present, or future physical, mental, or behavioral health or condition of an individual;

(ii) The provision of health care to an individual; or

(iii) The payment for the provision of health care to an individual.

(2) The term does not include:

(i) The age or gender of a consumer;

(ii) Demographic information about the consumer, including a consumer's residence address or e-mail address;

(iii) Any other information about a consumer that does not relate to the physical, mental, or behavioral health or condition of a consumer, including the existence or value of any insurance policy; or

(iv) Information that does not identify a specific consumer.

(l) *Person* means any individual, partnership, corporation, trust, estate cooperative, association, government or governmental subdivision or agency, or other entity.

■ 3. Subpart D is added to part 222 to read as follows:

Subpart D—Medical Information

Sec.
222.30 Obtaining or using medical information in connection with a determination of eligibility for credit.
222.31 Limits on redisclosure of information.
222.32 Sharing medical information with affiliates.

Subpart D—Medical Information

§ 222.30 Obtaining or using medical information in connection with a determination of eligibility for credit.

(a) *Scope.* This section applies to

(1) Any of the following that participates as a creditor in a transaction—

(i) A bank that is a member of the Federal Reserve System (other than national banks) and its subsidiaries;

(ii) A branch or Agency of a foreign bank (other than Federal branches, Federal Agencies, and insured State branches of foreign banks) and its subsidiaries;

(iii) A commercial lending company owned or controlled by foreign banks;

(iv) An organization operating under section 25 or 25A of the Federal Reserve Act (12 U.S.C. 601 *et seq.*, and 611 *et seq.*);

(v) A bank holding company and an affiliate of such holding company (other than depository institutions and consumer reporting agencies); or

(2) Any other person that participates as a creditor in a transaction involving a person described in paragraph (a)(1) of this section.

(b) *General prohibition on obtaining or using medical information.* (1) *In general.* A creditor may not obtain or use medical information pertaining to a consumer in connection with any determination of the consumer's eligibility, or continued eligibility, for credit, except as provided in this section.

(2) *Definitions.* (i) *Credit* has the same meaning as in section 702 of the Equal Credit Opportunity Act, 15 U.S.C. 1691a.

(ii) *Creditor* has the same meaning as in section 702 of the Equal Credit Opportunity Act, 15 U.S.C. 1691a.

(iii) *Eligibility, or continued eligibility, for credit* means the consumer's qualification or fitness to receive, or continue to receive, credit, including the terms on which credit is offered. The term does not include:

(A) Any determination of the consumer's qualification or fitness for employment, insurance (other than a credit insurance product), or other non-credit products or services;

(B) Authorizing, processing, or documenting a payment or transaction on behalf of the consumer in a manner that does not involve a determination of the consumer's eligibility, or continued eligibility, for credit; or

(C) Maintaining or servicing the consumer's account in a manner that does not involve a determination of the consumer's eligibility, or continued eligibility, for credit.

(c) *Rule of construction for obtaining and using unsolicited medical information.* (1) *In general.* A creditor does not obtain medical information in violation of the prohibition if it receives medical information pertaining to a consumer in connection with any determination of the consumer's eligibility, or continued eligibility, for credit without specifically requesting medical information.

(2) *Use of unsolicited medical information.* A creditor that receives unsolicited medical information in the manner described in paragraph (c)(1) of this section may use that information in connection with any determination of the consumer's eligibility, or continued eligibility, for credit to the extent the creditor can rely on at least one of the exceptions in § 222.30(d) or (e).

(3) *Examples.* A creditor does not obtain medical information in violation of the prohibition if, for example:

(i) In response to a general question regarding a consumer's debts or expenses, the creditor receives information that the consumer owes a debt to a hospital.

(ii) In a conversation with the creditor's loan officer, the consumer informs the creditor that the consumer has a particular medical condition.

(iii) In connection with a consumer's application for an extension of credit, the creditor requests a consumer report from a consumer reporting agency and receives medical information in the consumer report furnished by the agency even though the creditor did not specifically request medical information from the consumer reporting agency.

(d) *Financial information exception for obtaining and using medical information.* (1) *In general.* A creditor may obtain and use medical information pertaining to a consumer in connection with any determination of the consumer's eligibility, or continued eligibility, for credit so long as:

(i) The information is the type of information routinely used in making credit eligibility determinations, such as information relating to debts, expenses, income, benefits, assets, collateral, or the purpose of the loan, including the use of proceeds;

(ii) The creditor uses the medical information in a manner and to an extent that is no less favorable than it would use comparable information that is not medical information in a credit transaction; and

(iii) The creditor does not take the consumer's physical, mental, or behavioral health, condition or history, type of treatment, or prognosis into account as part of any such determination.

(2) *Examples.* (i) *Examples of the types of information routinely used in making credit eligibility determinations.* Paragraph (d)(1)(i) of this section permits a creditor, for example, to obtain and use information about:

(A) The dollar amount, repayment terms, repayment history, and similar information regarding medical debts to calculate, measure, or verify the repayment ability of the consumer, the use of proceeds, or the terms for granting credit;

(B) The value, condition, and lien status of a medical device that may serve as collateral to secure a loan;

(C) The dollar amount and continued eligibility for disability income or benefits related to health or a medical condition that is relied on as a source of repayment; or

(D) The identity of creditors to whom outstanding medical debts are owed in connection with an application for credit, including but not limited to, a transaction involving the consolidation of medical debts.

(ii) *Examples of uses of medical information consistent with the exception.* (A) A consumer includes on an application for credit information about two $20,000 debts. One debt is to a hospital; the other debt is to a retailer. The creditor contacts the hospital and the retailer to verify the amount and payment status of the debts. The creditor learns that both debts are more than 90 days past due. Any two debts of this size that are more than 90 days past due would disqualify the consumer under the creditor's established underwriting criteria. The creditor denies the application on the basis that the consumer has a poor repayment history on outstanding debts. The creditor has used medical information in a manner and to an extent no less favorable than it would use comparable non-medical information.

(B) A consumer indicates on an application for a $200,000 mortgage loan that she receives $15,000 in long-term disability income each year from her former employer and has no other income. Annual income of $15,000, regardless of source, would not be sufficient to support the requested amount of credit. The creditor denies the application on the basis that the projected debt-to-income ratio of the consumer does not meet the creditor's underwriting criteria. The creditor has used medical information in a manner and to an extent that is no less favorable than it would use comparable non-medical information.

(C) A consumer includes on an application for a $10,000 home equity loan that he has a $50,000 debt to a medical facility that specializes in treating a potentially terminal disease. The creditor contacts the medical facility to verify the debt and obtain the repayment history and current status of the loan. The creditor learns that the debt is current. The applicant meets the income and other requirements of the creditor's underwriting guidelines. The creditor grants the application. The creditor has used medical information in accordance with the exception.

(iii) *Examples of uses of medical information inconsistent with the exception.* (A) A consumer applies for $25,000 of credit and includes on the application information about a $50,000 debt to a hospital. The creditor contacts the hospital to verify the amount and payment status of the debt, and learns that the debt is current and that the consumer has no delinquencies in her repayment history. If the existing debt were instead owed to a retail department store, the creditor would approve the application and extend credit based on the amount and repayment history of the outstanding debt. The creditor, however, denies the application because the consumer is indebted to a hospital. The creditor has used medical information, here the identity of the medical creditor, in a manner and to an extent that is less favorable than it would use comparable non-medical information.

(B) A consumer meets with a loan officer of a creditor to apply for a mortgage loan. While filling out the loan application, the consumer informs the loan officer orally that she has a potentially terminal disease. The consumer meets the creditor's established requirements for the requested mortgage loan. The loan officer recommends to the credit committee that the consumer be denied credit because the consumer has that disease. The credit committee follows the loan officer's recommendation and denies the application because the consumer has a potentially terminal disease. The creditor has used medical information in a manner inconsistent with the exception by taking into account the consumer's physical, mental, or behavioral health, condition, or history, type of treatment, or prognosis as part of a determination of eligibility or continued eligibility for credit.

(C) A consumer who has an apparent medical condition, such as a consumer who uses a wheelchair or an oxygen tank, meets with a loan officer to apply for a home equity loan. The consumer meets the creditor's established requirements for the requested home equity loan and the creditor typically does not require consumers to obtain a debt cancellation contract, debt suspension agreement, or credit insurance product in connection with such loans. However, based on the consumer's apparent medical condition, the loan officer recommends to the credit committee that credit be extended to the consumer only if the consumer obtains a debt cancellation contract, debt suspension agreement, or credit insurance product. The credit committee agrees with the loan officer's recommendation. The loan officer informs the consumer that the consumer must obtain a debt cancellation contract, debt suspension agreement, or credit insurance product to qualify for the loan. The consumer obtains one of these products from a third party and the creditor approves the loan. The creditor has used medical information in a manner inconsistent with the exception by taking into account the consumer's

physical, mental, or behavioral health, condition, or history, type of treatment, or prognosis in setting conditions on the consumer's eligibility for credit.

(e) *Specific exceptions for obtaining and using medical information.* (1) *In general.* A creditor may obtain and use medical information pertaining to a consumer in connection with any determination of the consumer's eligibility, or continued eligibility, for credit—

(i) To determine whether the use of a power of attorney or legal representative that is triggered by a medical event or condition is necessary and appropriate or whether the consumer has the legal capacity to contract when a person seeks to exercise a power of attorney or act as legal representative for a consumer based on an asserted medical event or condition;

(ii) To comply with applicable requirements of local, State, or Federal laws;

(iii) To determine, at the consumer's request, whether the consumer qualifies for a legally permissible special credit program or credit-related assistance program that is—

(A) Designed to meet the special needs of consumers with medical conditions; and

(B) Established and administered pursuant to a written plan that—

(*1*) Identifies the class of persons that the program is designed to benefit; and

(*2*) Sets forth the procedures and standards for extending credit or providing other credit-related assistance under the program.

(iv) To the extent necessary for purposes of fraud prevention or detection;

(v) In the case of credit for the purpose of financing medical products or services, to determine and verify the medical purpose of a loan and the use of proceeds;

(vi) Consistent with safe and sound practices, if the consumer or the consumer's legal representative specifically requests that the creditor use medical information in determining the consumer's eligibility, or continued eligibility, for credit, to accommodate the consumer's particular circumstances, and such request is documented by the creditor;

(vii) Consistent with safe and sound practices, to determine whether the provisions of a forbearance practice or program that is triggered by a medical event or condition apply to a consumer;

(viii) To determine the consumer's eligibility for, the triggering of, or the reactivation of a debt cancellation contract or debt suspension agreement if a medical condition or event is a triggering event for the provision of benefits under the contract or agreement; or

(ix) To determine the consumer's eligibility for, the triggering of, or the reactivation of a credit insurance product if a medical condition or event is a triggering event for the provision of benefits under the product.

(2) *Example of determining eligibility for a special credit program or credit assistance program.* A not-for-profit organization establishes a credit assistance program pursuant to a written plan that is designed to assist disabled veterans in purchasing homes by subsidizing the down payment for the home purchase mortgage loans of qualifying veterans. The organization works through mortgage lenders and requires mortgage lenders to obtain medical information about the disability of any consumer that seeks to qualify for the program, use that information to verify the consumer's eligibility for the program, and forward that information to the organization. A consumer who is a veteran applies to a creditor for a home purchase mortgage loan. The creditor informs the consumer about the credit assistance program for disabled veterans and the consumer seeks to qualify for the program. Assuming that the program complies with all applicable law, including applicable fair lending laws, the creditor may obtain and use medical information about the medical condition and disability, if any, of the consumer to determine whether the consumer qualifies for the credit assistance program.

(3) *Examples of verifying the medical purpose of the loan or the use of proceeds.* (i) If a consumer applies for $10,000 of credit for the purpose of financing vision correction surgery, the creditor may verify with the surgeon that the procedure will be performed. If the surgeon reports that surgery will not be performed on the consumer, the creditor may use that medical information to deny the consumer's application for credit, because the loan would not be used for the stated purpose.

(ii) If a consumer applies for $10,000 of credit for the purpose of financing cosmetic surgery, the creditor may confirm the cost of the procedure with the surgeon. If the surgeon reports that the cost of the procedure is $5,000, the creditor may use that medical information to offer the consumer only $5,000 of credit.

(iii) A creditor has an established medical loan program for financing particular elective surgical procedures. The creditor receives a loan application from a consumer requesting $10,000 of credit under the established loan program for an elective surgical procedure. The consumer indicates on the application that the purpose of the loan is to finance an elective surgical procedure not eligible for funding under the guidelines of the established loan program. The creditor may deny the consumer's application because the purpose of the loan is not for a particular procedure funded by the established loan program.

(4) *Examples of obtaining and using medical information at the request of the consumer.* (i) If a consumer applies for a loan and specifically requests that the creditor consider the consumer's medical disability at the relevant time as an explanation for adverse payment history information in his credit report, the creditor may consider such medical information in evaluating the consumer's willingness and ability to repay the requested loan to accommodate the consumer's particular circumstances, consistent with safe and sound practices. The creditor may also decline to consider such medical information to accommodate the consumer, but may evaluate the consumer's application in accordance with its otherwise applicable underwriting criteria. The creditor may not deny the consumer's application or otherwise treat the consumer less favorably because the consumer specifically requested a medical accommodation, if the creditor would have extended the credit or treated the consumer more favorably under the creditor's otherwise applicable underwriting criteria.

(ii) If a consumer applies for a loan by telephone and explains that his income has been and will continue to be interrupted on account of a medical condition and that he expects to repay the loan by liquidating assets, the creditor may, but is not required to, evaluate the application using the sale of assets as the primary source of repayment, consistent with safe and sound practices, provided that the creditor documents the consumer's request by recording the oral conversation or making a notation of the request in the consumer's file.

(iii) If a consumer applies for a loan and the application form provides a space where the consumer may provide any other information or special circumstances, whether medical or non-medical, that the consumer would like the creditor to consider in evaluating the consumer's application, the creditor may use medical information provided by the consumer in that space on that application to accommodate the consumer's application for credit,

consistent with safe and sound practices, or may disregard that information.

(iv) If a consumer specifically requests that the creditor use medical information in determining the consumer's eligibility, or continued eligibility, for credit and provides the creditor with medical information for that purpose, and the creditor determines that it needs additional information regarding the consumer's circumstances, the creditor may request, obtain, and use additional medical information about the consumer as necessary to verify the information provided by the consumer or to determine whether to make an accommodation for the consumer. The consumer may decline to provide additional information, withdraw the request for an accommodation, and have the application considered under the creditor's otherwise applicable underwriting criteria.

(v) If a consumer completes and signs a credit application that is not for medical purpose credit and the application contains boilerplate language that routinely requests medical information from the consumer or that indicates that by applying for credit the consumer authorizes or consents to the creditor obtaining and using medical information in connection with a determination of the consumer's eligibility, or continued eligibility, for credit, the consumer has not specifically requested that the creditor obtain and use medical information to accommodate the consumer's particular circumstances.

(5) *Example of a forbearance practice or program.* After an appropriate safety and soundness review, a creditor institutes a program that allows consumers who are or will be hospitalized to defer payments as needed for up to three months, without penalty, if the credit account has been open for more than one year and has not previously been in default, and the consumer provides confirming documentation at an appropriate time. A consumer is hospitalized and does not pay her bill for a particular month. This consumer has had a credit account with the creditor for more than one year and has not previously been in default. The creditor attempts to contact the consumer and speaks with the consumer's adult child, who is not the consumer's legal representative. The adult child informs the creditor that the consumer is hospitalized and is unable to pay the bill at that time. The creditor defers payments for up to three months, without penalty, for the hospitalized consumer and sends the consumer a letter confirming this practice and the date on which the next payment will be due.

§ 222.31 Limits on redisclosure of information.

(a) *Scope.* This section applies to banks that are members of the Federal Reserve System (other than national banks) and their respective operating subsidiaries, branches and agencies of foreign banks (other than Federal branches, Federal Agencies, and insured State branches of foreign banks), commercial lending companies owned or controlled by foreign banks, organizations operating under section 25 or 25A of the Federal Reserve Act (12 U.S.C. 601 *et seq.*, and 611 *et seq.*), and bank holding companies and affiliates of such holding companies (other than depository institutions and consumer reporting agencies).

(b) *Limits on redisclosure.* If a person described in paragraph (a) of this section receives medical information about a consumer from a consumer reporting agency or its affiliate, the person must not disclose that information to any other person, except as necessary to carry out the purpose for which the information was initially disclosed, or as otherwise permitted by statute, regulation, or order.

§ 222.32 Sharing medical information with affiliates.

(a) *Scope.* This section applies to banks that are members of the Federal Reserve System (other than national banks) and their respective operating subsidiaries, branches and agencies of foreign banks (other than Federal branches, Federal Agencies, and insured State branches of foreign banks), commercial lending companies owned or controlled by foreign banks, organizations operating under section 25 or 25A of the Federal Reserve Act (12 U.S.C. 601 *et seq.*, and 611 *et seq.*).

(b) *In general.* The exclusions from the term ''consumer report'' in section 603(d)(2) of the Act that allow the sharing of information with affiliates do not apply to a person described in paragraph (a) of this section if that person communicates to an affiliate—

(1) Medical information;

(2) An individualized list or description based on the payment transactions of the consumer for medical products or services; or

(3) An aggregate list of identified consumers based on payment transactions for medical products or services.

(c) Exceptions. A person described in paragraph (a) of this section may rely on the exclusions from the term ''consumer report'' in section 603(d)(2) of the Act to communicate the information in paragraph (b) of this section to an affiliate—

(1) In connection with the business of insurance or annuities (including the activities described in section 18B of the model Privacy of Consumer Financial and Health Information Regulation issued by the National Association of Insurance Commissioners, as in effect on January 1, 2003);

(2) For any purpose permitted without authorization under the regulations promulgated by the Department of Health and Human Services pursuant to the Health Insurance Portability and Accountability Act of 1996 (HIPAA);

(3) For any purpose referred to in section 1179 of HIPAA;

(4) For any purpose described in section 502(e) of the Gramm-Leach-Bliley Act;

(5) In connection with a determination of the consumer's eligibility, or continued eligibility, for credit consistent with § 222.30 of this part; or

(6) As otherwise permitted by order of the Board.

■ 4. A new part 232 is added to read as follows:

PART 232—OBTAINING AND USING MEDICAL INFORMATION IN CONNECTION WITH CREDIT (REGULATION FF)

Sec.

232.1 Scope, general prohibition and definitions.
232.2 Rule of construction for obtaining and using unsolicited medical information.
232.3 Financial information exception for obtaining and using medical information.
232.4 Specific exceptions for obtaining and using medical information.

Authority: 15 U.S.C. 1681b.

§ 232.1 Scope, general prohibition and definitions.

(a) *Scope.* This part applies to creditors, as defined in paragraph (c)(3) of this section, except for creditors that are subject to §§ 41.30, 222.30, 334.30, 571.30, or 717.30.

(b) *In general.* A creditor may not obtain or use medical information pertaining to a consumer in connection with any determination of the consumer's eligibility, or continued eligibility, for credit, except as provided in this section.

(c) *Definitions.* (1) *Consumer* means an individual.

(2) *Credit* has the same meaning as in section 702 of the Equal Credit Opportunity Act, 15 U.S.C. 1691a.

(3) *Creditor* has the same meaning as in section 702 of the Equal Credit Opportunity Act, 15 U.S.C. 1691a.

(4) *Eligibility, or continued eligibility, for credit* means the consumer's qualification or fitness to receive, or continue to receive, credit, including the terms on which credit is offered. The term does not include:

(i) Any determination of the consumer's qualification or fitness for employment, insurance (other than a credit insurance product), or other non-credit products or services;

(ii) Authorizing, processing, or documenting a payment or transaction on behalf of the consumer in a manner that does not involve a determination of the consumer's eligibility, or continued eligibility, for credit; or

(iii) Maintaining or servicing the consumer's account in a manner that does not involve a determination of the consumer's eligibility, or continued eligibility, for credit.

(5) *Medical information* means:

(i) Information or data, whether oral or recorded, in any form or medium, created by or derived from a health care provider or the consumer, that relates to—

(A) The past, present, or future physical, mental, or behavioral health or condition of an individual;

(B) The provision of health care to an individual; or

(C) The payment for the provision of health care to an individual.

(ii) The term does not include:

(A) The age or gender of a consumer;

(B) Demographic information about the consumer, including a consumer's residence address or e-mail address;

(C) Any other information about a consumer that does not relate to the physical, mental, or behavioral health or condition of a consumer, including the existence or value of any insurance policy; or

(D) Information that does not identify a specific consumer.

(6) *Person* means any individual, partnership, corporation, trust, estate cooperative, association, government or governmental subdivision or agency, or other entity.

§ 232.2 Rule of construction for obtaining and using unsolicited medical information.

(a) *In general.* A creditor does not obtain medical information in violation of the prohibition if it receives medical information pertaining to a consumer in connection with any determination of the consumer's eligibility, or continued eligibility, for credit without specifically requesting medical information.

(b) *Use of unsolicited medical information.* A creditor that receives unsolicited medical information in the manner described in paragraph (a) of this section may use that information in connection with any determination of the consumer's eligibility, or continued eligibility, for credit to the extent the creditor can rely on at least one of the exceptions in § 232.3 or § 232.4.

(c) *Examples.* A creditor does not obtain medical information in violation of the prohibition if, for example:

(1) In response to a general question regarding a consumer's debts or expenses, the creditor receives information that the consumer owes a debt to a hospital.

(2) In a conversation with the creditor's loan officer, the consumer informs the creditor that the consumer has a particular medical condition.

(3) In connection with a consumer's application for an extension of credit, the creditor requests a consumer report from a consumer reporting agency and receives medical information in the consumer report furnished by the agency even though the creditor did not specifically request medical information from the consumer reporting agency.

§ 232.3 Financial information exception for obtaining and using medical information.

(a) *In general.* A creditor may obtain and use medical information pertaining to a consumer in connection with any determination of the consumer's eligibility, or continued eligibility, for credit so long as:

(1) The information is the type of information routinely used in making credit eligibility determinations, such as information relating to debts, expenses, income, benefits, assets, collateral, or the purpose of the loan, including the use of proceeds;

(2) The creditor uses the medical information in a manner and to an extent that is no less favorable than it would use comparable information that is not medical information in a credit transaction; and

(3) The creditor does not take the consumer's physical, mental, or behavioral health, condition or history, type of treatment, or prognosis into account as part of any such determination.

(b) *Examples.* (1) *Examples of the types of information routinely used in making credit eligibility determinations.* Paragraph (a)(1) of this section permits a creditor, for example, to obtain and use information about:

(i) The dollar amount, repayment terms, repayment history, and similar information regarding medical debts to calculate, measure, or verify the repayment ability of the consumer, the use of proceeds, or the terms for granting credit;

(ii) The value, condition, and lien status of a medical device that may serve as collateral to secure a loan;

(iii) The dollar amount and continued eligibility for disability income or benefits related to health or a medical condition that is relied on as a source of repayment; or

(iv) The identity of creditors to whom outstanding medical debts are owed in connection with an application for credit, including but not limited to, a transaction involving the consolidation of medical debts.

(2) *Examples of uses of medical information consistent with the exception.* (i) A consumer includes on an application for credit information about two $20,000 debts. One debt is to a hospital; the other debt is to a retailer. The creditor contacts the hospital and the retailer to verify the amount and payment status of the debts. The creditor learns that both debts are more than 90 days past due. Any two debts of this size that are more than 90 days past due would disqualify the consumer under the creditor's established underwriting criteria. The creditor denies the application on the basis that the consumer has a poor repayment history on outstanding debts. The creditor has used medical information in a manner and to an extent no less favorable than it would use comparable non-medical information.

(ii) A consumer indicates on an application for a $200,000 mortgage loan that she receives $15,000 in long-term disability income each year from her former employer and has no other income. Annual income of $15,000, regardless of source, would not be sufficient to support the requested amount of credit. The creditor denies the application on the basis that the projected debt-to-income ratio of the consumer does not meet the creditor's underwriting criteria. The creditor has used medical information in a manner and to an extent that is no less favorable than it would use comparable non-medical information.

(iii) A consumer includes on an application for a $10,000 home equity loan that he has a $50,000 debt to a medical facility that specializes in treating a potentially terminal disease. The creditor contacts the medical facility to verify the debt and obtain the repayment history and current status of the loan. The creditor learns that the debt is current. The applicant meets the income and other requirements of the creditor's underwriting guidelines. The creditor grants the application. The

creditor has used medical information in accordance with the exception.

(3) *Examples of uses of medical information inconsistent with the exception.* (i) A consumer applies for $25,000 of credit and includes on the application information about a $50,000 debt to a hospital. The creditor contacts the hospital to verify the amount and payment status of the debt, and learns that the debt is current and that the consumer has no delinquencies in her repayment history. If the existing debt were instead owed to a retail department store, the creditor would approve the application and extend credit based on the amount and repayment history of the outstanding debt. The creditor, however, denies the application because the consumer is indebted to a hospital. The creditor has used medical information, here the identity of the medical creditor, in a manner and to an extent that is less favorable than it would use comparable non-medical information.

(ii) A consumer meets with a loan officer of a creditor to apply for a mortgage loan. While filling out the loan application, the consumer informs the loan officer orally that she has a potentially terminal disease. The consumer meets the creditor's established requirements for the requested mortgage loan. The loan officer recommends to the credit committee that the consumer be denied credit because the consumer has that disease. The credit committee follows the loan officer's recommendation and denies the application because the consumer has a potentially terminal disease. The creditor has used medical information in a manner inconsistent with the exception by taking into account the consumer's physical, mental, or behavioral health, condition, or history, type of treatment, or prognosis as part of a determination of eligibility or continued eligibility for credit.

(iii) A consumer who has an apparent medical condition, such as a consumer who uses a wheelchair or an oxygen tank, meets with a loan officer to apply for a home equity loan. The consumer meets the creditor's established requirements for the requested home equity loan and the creditor typically does not require consumers to obtain a debt cancellation contract, debt suspension agreement, or credit insurance product in connection with such loans. However, based on the consumer's apparent medical condition, the loan officer recommends to the credit committee that credit be extended to the consumer only if the consumer obtains a debt cancellation contract, debt suspension agreement, or credit insurance product. The credit committee agrees with the loan officer's recommendation. The loan officer informs the consumer that the consumer must obtain a debt cancellation contract, debt suspension agreement, or credit insurance product to qualify for the loan. The consumer obtains one of these products from a third party and the creditor approves the loan. The creditor has used medical information in a manner inconsistent with the exception by taking into account the consumer's physical, mental, or behavioral health, condition, or history, type of treatment, or prognosis in setting conditions on the consumer's eligibility for credit.

§ 232.4 Specific exceptions for obtaining and using medical information.

(a) *In general.* A creditor may obtain and use medical information pertaining to a consumer in connection with any determination of the consumer's eligibility, or continued eligibility, for credit—

(1) To determine whether the use of a power of attorney or legal representative that is triggered by a medical event or condition is necessary and appropriate or whether the consumer has the legal capacity to contract when a person seeks to exercise a power of attorney or act as legal representative for a consumer based on an asserted medical event or condition;

(2) To comply with applicable requirements of local, State, or Federal laws;

(3) To determine, at the consumer's request, whether the consumer qualifies for a legally permissible special credit program or credit-related assistance program that is—

(i) Designed to meet the special needs of consumers with medical conditions; and

(ii) Established and administered pursuant to a written plan that—

(A) Identifies the class of persons that the program is designed to benefit; and

(B) Sets forth the procedures and standards for extending credit or providing other credit-related assistance under the program.

(4) To the extent necessary for purposes of fraud prevention or detection;

(5) In the case of credit for the purpose of financing medical products or services, to determine and verify the medical purpose of a loan and the use of proceeds;

(6) Consistent with safe and sound practices, if the consumer or the consumer's legal representative specifically requests that the creditor use medical information in determining the consumer's eligibility, or continued eligibility, for credit, to accommodate the consumer's particular circumstances, and such request is documented by the creditor;

(7) Consistent with safe and sound practices, to determine whether the provisions of a forbearance practice or program that is triggered by a medical event or condition apply to a consumer;

(8) To determine the consumer's eligibility for, the triggering of, or the reactivation of a debt cancellation contract or debt suspension agreement if a medical condition or event is a triggering event for the provision of benefits under the contract or agreement; or

(9) To determine the consumer's eligibility for, the triggering of, or the reactivation of a credit insurance product if a medical condition or event is a triggering event for the provision of benefits under the product.

(b) *Example of determining eligibility for a special credit program or credit assistance program.* A not-for-profit organization establishes a credit assistance program pursuant to a written plan that is designed to assist disabled veterans in purchasing homes by subsidizing the down payment for the home purchase mortgage loans of qualifying veterans. The organization works through mortgage lenders and requires mortgage lenders to obtain medical information about the disability of any consumer that seeks to qualify for the program, use that information to verify the consumer's eligibility for the program, and forward that information to the organization. A consumer who is a veteran applies to a creditor for a home purchase mortgage loan. The creditor informs the consumer about the credit assistance program for disabled veterans and the consumer seeks to qualify for the program. Assuming that the program complies with all applicable law, including applicable fair lending laws, the creditor may obtain and use medical information about the medical condition and disability, if any, of the consumer to determine whether the consumer qualifies for the credit assistance program.

(c) *Examples of verifying the medical purpose of the loan or the use of proceeds.* (1) If a consumer applies for $10,000 of credit for the purpose of financing vision correction surgery, the creditor may verify with the surgeon that the procedure will be performed. If the surgeon reports that surgery will not be performed on the consumer, the creditor may use that medical information to deny the consumer's application for credit, because the loan

would not be used for the stated purpose.

(2) If a consumer applies for $10,000 of credit for the purpose of financing cosmetic surgery, the creditor may confirm the cost of the procedure with the surgeon. If the surgeon reports that the cost of the procedure is $5,000, the creditor may use that medical information to offer the consumer only $5,000 of credit.

(3) A creditor has an established medical loan program for financing particular elective surgical procedures. The creditor receives a loan application from a consumer requesting $10,000 of credit under the established loan program for an elective surgical procedure. The consumer indicates on the application that the purpose of the loan is to finance an elective surgical procedure not eligible for funding under the guidelines of the established loan program. The creditor may deny the consumer's application because the purpose of the loan is not for a particular procedure funded by the established loan program.

(d) *Examples of obtaining and using medical information at the request of the consumer.* (1) If a consumer applies for a loan and specifically requests that the creditor consider the consumer's medical disability at the relevant time as an explanation for adverse payment history information in his credit report, the creditor may consider such medical information in evaluating the consumer's willingness and ability to repay the requested loan to accommodate the consumer's particular circumstances, consistent with safe and sound practices. The creditor may also decline to consider such medical information to accommodate the consumer, but may evaluate the consumer's application in accordance with its otherwise applicable underwriting criteria. The creditor may not deny the consumer's application or otherwise treat the consumer less favorably because the consumer specifically requested a medical accommodation, if the creditor would have extended the credit or treated the consumer more favorably under the creditor's otherwise applicable underwriting criteria.

(2) If a consumer applies for a loan by telephone and explains that his income has been and will continue to be interrupted on account of a medical condition and that he expects to repay the loan liquidating assets, the creditor may, but is not required to, evaluate the application using the sale of assets as the primary source of repayment, consistent with safe and sound practices, provided that the creditor documents the consumer's request by recording the oral conversation or making a notation of the request in the consumer's file.

(3) If a consumer applies for a loan and the application form provides a space where the consumer may provide any other information or special circumstances, whether medical or non-medical, that the consumer would like the creditor to consider in evaluating the consumer's application, the creditor may use medical information provided by the consumer in that space on that application to accommodate the consumer's application for credit, consistent with safe and sound practices, or may disregard that information.

(4) If a consumer specifically requests that the creditor use medical information in determining the consumer's eligibility, or continued eligibility, for credit and provides the creditor with medical information for that purpose, and the creditor determines that it needs additional information regarding the consumer's circumstances, the creditor may request, obtain, and use additional medical information about the consumer as necessary to verify the information provided by the consumer or to determine whether to make an accommodation for the consumer. The consumer may decline to provide additional information, withdraw the request for an accommodation, and have the application considered under the creditor's otherwise applicable underwriting criteria.

(5) If a consumer completes and signs a credit application that is not for medical purpose credit and the application contains boilerplate language that routinely requests medical information from the consumer or that indicates that by applying for credit the consumer authorizes or consents to the creditor obtaining and using medical information in connection with a determination of the consumer's eligibility, or continued eligibility, for credit, the consumer has not specifically requested that the creditor obtain and use medical information to accommodate the consumer's particular circumstances.

(e) *Example of a forbearance practice or program.* After an appropriate safety and soundness review, a creditor institutes a program that allows consumers who are or will be hospitalized to defer payments as needed for up to three months, without penalty, if the credit account has been open for more than one year and has not previously been in default, and the consumer provides confirming documentation at an appropriate time. A consumer is hospitalized and does not pay her bill for a particular month. This consumer has had a credit account with the creditor for more than one year and has not previously been in default. The creditor attempts to contact the consumer and speaks with the consumer's adult child, who is not the consumer's legal representative. The adult child informs the creditor that the consumer is hospitalized and is unable to pay the bill at that time. The creditor defers payments for up to three months, without penalty, for the hospitalized consumer and sends the consumer a letter confirming this practice and the date on which the next payment will be due.

Federal Deposit Insurance Corporation

12 CFR Chapter III.

Authority and Issuance

■ For the reasons set forth in the joint preamble, the Federal Deposit Insurance Corporation amends part 334 of chapter III of title 12 of the Code of Federal Regulations as follows:

PART 334—FAIR CREDIT REPORTING

■ 1. The authority citation for part 334 is revised to read as follows:

Authority: 12 U.S.C. 1819 (Tenth) and 1818; 15 U.S.C. 1681b and 1681s.

■ 2. Subpart A is added to part 334 to read as follows:

Subpart A—General Provisions

Sec.
334.1 [Reserved]
334.2 Examples.
334.3 Definitions.

Subpart A—General Provisions

§ 334.1 [Reserved]

§ 334.2 Examples.

The examples in this part are not exclusive. Compliance with an example, to the extent applicable, constitutes compliance with this part. Examples in a paragraph illustrate only the issue described in the paragraph and do not illustrate any other issue that may arise in this part.

§ 334.3 Definitions.

As used in this part, unless the context requires otherwise:

(a) *Act* means the Fair Credit Reporting Act (15 U.S.C. 1681 *et seq.*).

(b) *Affiliate* means any company that is related by common ownership or common corporate control with another company.

(c) [Reserved]

(d) *Company* means any corporation, limited liability company, business

trust, general or limited partnership, association, or similar organization.

(e) *Consumer* means an individual.

(f) [Reserved]

(g) [Reserved]

(h) [Reserved]

(i) *Common ownership or common corporate control* means a relationship between two companies under which:

(1) One company has, with respect to the other company:

(i) Ownership, control, or power to vote 25 percent or more of the outstanding shares of any class of voting security of a company, directly or indirectly, or acting through one or more other persons;

(ii) Control in any manner over the election of a majority of the directors, trustees, or general partners (or individuals exercising similar functions) of a company; or

(iii) The power to exercise, directly or indirectly, a controlling influence over the management or policies of a company, as the FDIC determines; or

(2) Any other person has, with respect to both companies, a relationship described in paragraphs (i)(1)(i)–(i)(1)(iii) of this section.

(j) [Reserved]

(k) *Medical information* means:

(1) Information or data, whether oral or recorded, in any form or medium, created by or derived from a health care provider or the consumer, that relates to—

(i) The past, present, or future physical, mental, or behavioral health or condition of an individual;

(ii) The provision of health care to an individual; or

(iii) The payment for the provision of health care to an individual.

(2) The term does not include:

(i) The age or gender of a consumer;

(ii) Demographic information about the consumer, including a consumer's residence address or e-mail address;

(iii) Any other information about a consumer that does not relate to the physical, mental, or behavioral health or condition of a consumer, including the existence or value of any insurance policy; or

(iv) Information that does not identify a specific consumer.

(l) *Person* means any individual, partnership, corporation, trust, estate cooperative, association, government or governmental subdivision or agency, or other entity.

■ 3. Subpart D is added to part 334 to read as follows:

Subpart D—Medical Information

§ 334.30 Obtaining or using medical information in connection with a determination of eligibility for credit.

(a) *Scope.* This section applies to:

(1) Any of the following that participates as a creditor in a transaction—

(i) A State bank insured by the FDIC (other than members of the Federal Reserve System);

(ii) An insured State branch of a foreign bank; or

(2) Any other person that participates as a creditor in a transaction involving a person described in paragraph (a)(1) of this section.

(b) *General prohibition on obtaining or using medical information.* (1) *In general.* A creditor may not obtain or use medical information pertaining to a consumer in connection with any determination of the consumer's eligibility, or continued eligibility, for credit, except as provided in this section.

(2) *Definitions.* (i) *Credit* has the same meaning as in section 702 of the Equal Credit Opportunity Act, 15 U.S.C. 1691a.

(ii) *Creditor* has the same meaning as in section 702 of the Equal Credit Opportunity Act, 15 U.S.C. 1691a.

(iii) *Eligibility, or continued eligibility, for credit* means the consumer's qualification or fitness to receive, or continue to receive, credit, including the terms on which credit is offered. The term does not include:

(A) Any determination of the consumer's qualification or fitness for employment, insurance (other than a credit insurance product), or other non-credit products or services;

(B) Authorizing, processing, or documenting a payment or transaction on behalf of the consumer in a manner that does not involve a determination of the consumer's eligibility, or continued eligibility, for credit; or

(C) Maintaining or servicing the consumer's account in a manner that does not involve a determination of the consumer's eligibility, or continued eligibility, for credit.

(c) *Rule of construction for obtaining and using unsolicited medical information.* (1) *In general.* A creditor does not obtain medical information in violation of the prohibition if it receives medical information pertaining to a consumer in connection with any determination of the consumer's eligibility, or continued eligibility, for credit without specifically requesting medical information.

(2) *Use of unsolicited medical information.* A creditor that receives unsolicited medical information in the manner described in paragraph (c)(1) of this section may use that information in connection with any determination of the consumer's eligibility, or continued eligibility, for credit to the extent the creditor can rely on at least one of the exceptions in § 334.30(d) or (e).

(3) *Examples.* A creditor does not obtain medical information in violation of the prohibition if, for example:

(i) In response to a general question regarding a consumer's debts or expenses, the creditor receives information that the consumer owes a debt to a hospital.

(ii) In a conversation with the creditor's loan officer, the consumer informs the creditor that the consumer has a particular medical condition.

(iii) In connection with a consumer's application for an extension of credit, the creditor requests a consumer report from a consumer reporting agency and receives medical information in the consumer report furnished by the agency even though the creditor did not specifically request medical information from the consumer reporting agency.

(d) *Financial information exception for obtaining and using medical information.* (1) *In general.* A creditor may obtain and use medical information pertaining to a consumer in connection with any determination of the consumer's eligibility, or continued eligibility, for credit so long as:

(i) The information is the type of information routinely used in making credit eligibility determinations, such as information relating to debts, expenses, income, benefits, assets, collateral, or the purpose of the loan, including the use of proceeds;

(ii) The creditor uses the medical information in a manner and to an extent that is no less favorable than it would use comparable information that is not medical information in a credit transaction; and

(iii) The creditor does not take the consumer's physical, mental, or behavioral health, condition or history, type of treatment, or prognosis into account as part of any such determination.

(2) *Examples.* (i) *Examples of the types of information routinely used in making credit eligibility determinations.* Paragraph (d)(1)(i) of this section permits a creditor, for example, to obtain and use information about:

(A) The dollar amount, repayment terms, repayment history, and similar information regarding medical debts to calculate, measure, or verify the repayment ability of the consumer, the use of proceeds, or the terms for granting credit;

(B) The value, condition, and lien status of a medical device that may serve as collateral to secure a loan;

(C) The dollar amount and continued eligibility for disability income or benefits related to health or a medical condition that is relied on as a source of repayment; or

(D) The identity of creditors to whom outstanding medical debts are owed in connection with an application for credit, including but not limited to, a transaction involving the consolidation of medical debts.

(ii) *Examples of uses of medical information consistent with the exception.* (A) A consumer includes on an application for credit information about two $20,000 debts. One debt is to a hospital; the other debt is to a retailer. The creditor contacts the hospital and the retailer to verify the amount and payment status of the debts. The creditor learns that both debts are more than 90 days past due. Any two debts of this size that are more than 90 days past due would disqualify the consumer under the creditor's established underwriting criteria. The creditor denies the application on the basis that the consumer has a poor repayment history on outstanding debts. The creditor has used medical information in a manner and to an extent no less favorable than it would use comparable non-medical information.

(B) A consumer indicates on an application for a $200,000 mortgage loan that she receives $15,000 in long-term disability income each year from her former employer and has no other income. Annual income of $15,000, regardless of source, would not be sufficient to support the requested amount of credit. The creditor denies the application on the basis that the projected debt-to-income ratio of the consumer does not meet the creditor's underwriting criteria. The creditor has used medical information in a manner and to an extent that is no less favorable than it would use comparable non-medical information.

(C) A consumer includes on an application for a $10,000 home equity loan that he has a $50,000 debt to a medical facility that specializes in treating a potentially terminal disease. The creditor contacts the medical facility to verify the debt and obtain the repayment history and current status of the loan. The creditor learns that the debt is current. The applicant meets the income and other requirements of the creditor's underwriting guidelines. The creditor grants the application. The creditor has used medical information in accordance with the exception.

(iii) *Examples of uses of medical information inconsistent with the exception.* (A) A consumer applies for $25,000 of credit and includes on the application information about a $50,000 debt to a hospital. The creditor contacts the hospital to verify the amount and payment status of the debt, and learns that the debt is current and that the consumer has no delinquencies in her repayment history. If the existing debt were instead owed to a retail department store, the creditor would approve the application and extend credit based on the amount and repayment history of the outstanding debt. The creditor, however, denies the application because the consumer is indebted to a hospital. The creditor has used medical information, here the identity of the medical creditor, in a manner and to an extent that is less favorable than it would use comparable non-medical information.

(B) A consumer meets with a loan officer of a creditor to apply for a mortgage loan. While filling out the loan application, the consumer informs the loan officer orally that she has a potentially terminal disease. The consumer meets the creditor's established requirements for the requested mortgage loan. The loan officer recommends to the credit committee that the consumer be denied credit because the consumer has that disease. The credit committee follows the loan officer's recommendation and denies the application because the consumer has a potentially terminal disease. The creditor has used medical information in a manner inconsistent with the exception by taking into account the consumer's physical, mental, or behavioral health, condition, or history, type of treatment, or prognosis as part of a determination of eligibility or continued eligibility for credit.

(C) A consumer who has an apparent medical condition, such as a consumer who uses a wheelchair or an oxygen tank, meets with a loan officer to apply for a home equity loan. The consumer meets the creditor's established requirements for the requested home equity loan and the creditor typically does not require consumers to obtain a debt cancellation contract, debt suspension agreement, or credit insurance product in connection with such loans. However, based on the consumer's apparent medical condition, the loan officer recommends to the credit committee that credit be extended to the consumer only if the consumer obtains a debt cancellation contract, debt suspension agreement, or credit insurance product. The credit committee agrees with the loan officer's recommendation. The loan officer informs the consumer that the consumer must obtain a debt cancellation contract, debt suspension agreement, or credit insurance product to qualify for the loan. The consumer obtains one of these products from a third party and the creditor approves the loan. The creditor has used medical information in a manner inconsistent with the exception by taking into account the consumer's physical, mental, or behavioral health, condition, or history, type of treatment, or prognosis in setting conditions on the consumer's eligibility for credit.

(e) *Specific exceptions for obtaining and using medical information.* (1) *In general.* A creditor may obtain and use medical information pertaining to a consumer in connection with any determination of the consumer's eligibility, or continued eligibility, for credit—

(i) To determine whether the use of a power of attorney or legal representative that is triggered by a medical event or condition is necessary and appropriate or whether the consumer has the legal capacity to contract when a person seeks to exercise a power of attorney or act as legal representative for a consumer based on an asserted medical event or condition;

(ii) To comply with applicable requirements of local, State, or Federal laws;

(iii) To determine, at the consumer's request, whether the consumer qualifies for a legally permissible special credit program or credit-related assistance program that is—

(A) Designed to meet the special needs of consumers with medical conditions; and

(B) Established and administered pursuant to a written plan that—

(*1*) Identifies the class of persons that the program is designed to benefit; and

(*2*) Sets forth the procedures and standards for extending credit or providing other credit-related assistance under the program.

(iv) To the extent necessary for purposes of fraud prevention or detection;

(v) In the case of credit for the purpose of financing medical products or services, to determine and verify the medical purpose of a loan and the use of proceeds;

(vi) Consistent with safe and sound practices, if the consumer or the consumer's legal representative specifically requests that the creditor use medical information in determining the consumer's eligibility, or continued eligibility, for credit, to accommodate the consumer's particular

circumstances, and such request is documented by the creditor;

(vii) Consistent with safe and sound practices, to determine whether the provisions of a forbearance practice or program that is triggered by a medical event or condition apply to a consumer;

(viii) To determine the consumer's eligibility for, the triggering of, or the reactivation of a debt cancellation contract or debt suspension agreement if a medical condition or event is a triggering event for the provision of benefits under the contract or agreement; or

(ix) To determine the consumer's eligibility for, the triggering of, or the reactivation of a credit insurance product if a medical condition or event is a triggering event for the provision of benefits under the product.

(2) *Example of determining eligibility for a special credit program or credit assistance program.* A not-for-profit organization establishes a credit assistance program pursuant to a written plan that is designed to assist disabled veterans in purchasing homes by subsidizing the down payment for the home purchase mortgage loans of qualifying veterans. The organization works through mortgage lenders and requires mortgage lenders to obtain medical information about the disability of any consumer that seeks to qualify for the program, use that information to verify the consumer's eligibility for the program, and forward that information to the organization. A consumer who is a veteran applies to a creditor for a home purchase mortgage loan. The creditor informs the consumer about the credit assistance program for disabled veterans and the consumer seeks to qualify for the program. Assuming that the program complies with all applicable law, including applicable fair lending laws, the creditor may obtain and use medical information about the medical condition and disability, if any, of the consumer to determine whether the consumer qualifies for the credit assistance program.

(3) *Examples of verifying the medical purpose of the loan or the use of proceeds.* (i) If a consumer applies for $10,000 of credit for the purpose of financing vision correction surgery, the creditor may verify with the surgeon that the procedure will be performed. If the surgeon reports that surgery will not be performed on the consumer, the creditor may use that medical information to deny the consumer's application for credit, because the loan would not be used for the stated purpose.

(ii) If a consumer applies for $10,000 of credit for the purpose of financing cosmetic surgery, the creditor may confirm the cost of the procedure with the surgeon. If the surgeon reports that the cost of the procedure is $5,000, the creditor may use that medical information to offer the consumer only $5,000 of credit.

(iii) A creditor has an established medical loan program for financing particular elective surgical procedures. The creditor receives a loan application from a consumer requesting $10,000 of credit under the established loan program for an elective surgical procedure. The consumer indicates on the application that the purpose of the loan is to finance an elective surgical procedure not eligible for funding under the guidelines of the established loan program. The creditor may deny the consumer's application because the purpose of the loan is not for a particular procedure funded by the established loan program.

(4) *Examples of obtaining and using medical information at the request of the consumer.* (i) If a consumer applies for a loan and specifically requests that the creditor consider the consumer's medical disability at the relevant time as an explanation for adverse payment history information in his credit report, the creditor may consider such medical information in evaluating the consumer's willingness and ability to repay the requested loan to accommodate the consumer's particular circumstances, consistent with safe and sound practices. The creditor may also decline to consider such medical information to accommodate the consumer, but may evaluate the consumer's application in accordance with its otherwise applicable underwriting criteria. The creditor may not deny the consumer's application or otherwise treat the consumer less favorably because the consumer specifically requested a medical accommodation, if the creditor would have extended the credit or treated the consumer more favorably under the creditor's otherwise applicable underwriting criteria.

(ii) If a consumer applies for a loan by telephone and explains that his income has been and will continue to be interrupted on account of a medical condition and that he expects to repay the loan by liquidating assets, the creditor may, but is not required to, evaluate the application using the sale of assets as the primary source of repayment, consistent with safe and sound practices, provided that the creditor documents the consumer's request by recording the oral conversation or making a notation of the request in the consumer's file.

(iii) If a consumer applies for a loan and the application form provides a space where the consumer may provide any other information or special circumstances, whether medical or non-medical, that the consumer would like the creditor to consider in evaluating the consumer's application, the creditor may use medical information provided by the consumer in that space on that application to accommodate the consumer's application for credit, consistent with safe and sound practices, or may disregard that information.

(iv) If a consumer specifically requests that the creditor use medical information in determining the consumer's eligibility, or continued eligibility, for credit and provides the creditor with medical information for that purpose, and the creditor determines that it needs additional information regarding the consumer's circumstances, the creditor may request, obtain, and use additional medical information about the consumer as necessary to verify the information provided by the consumer or to determine whether to make an accommodation for the consumer. The consumer may decline to provide additional information, withdraw the request for an accommodation, and have the application considered under the creditor's otherwise applicable underwriting criteria.

(v) If a consumer completes and signs a credit application that is not for medical purpose credit and the application contains boilerplate language that routinely requests medical information from the consumer or that indicates that by applying for credit the consumer authorizes or consents to the creditor obtaining and using medical information in connection with a determination of the consumer's eligibility, or continued eligibility, for credit, the consumer has not specifically requested that the creditor obtain and use medical information to accommodate the consumer's particular circumstances.

(5) *Example of a forbearance practice or program.* After an appropriate safety and soundness review, a creditor institutes a program that allows consumers who are or will be hospitalized to defer payments as needed for up to three months, without penalty, if the credit account has been open for more than one year and has not previously been in default, and the consumer provides confirming documentation at an appropriate time. A consumer is hospitalized and does not pay her bill for a particular month. This consumer has had a credit account

with the creditor for more than one year and has not previously been in default. The creditor attempts to contact the consumer and speaks with the consumer's adult child, who is not the consumer's legal representative. The adult child informs the creditor that the consumer is hospitalized and is unable to pay the bill at that time. The creditor defers payments for up to three months, without penalty, for the hospitalized consumer and sends the consumer a letter confirming this practice and the date on which the next payment will be due.

§ 334.31 Limits on redisclosure of information.

(a) *Scope.* This section applies to State banks insured by the FDIC (other than members of the Federal Reserve System) and insured State branches of foreign banks.

(b) *Limits on redisclosure.* If a person described in paragraph (a) of this section receives medical information about a consumer from a consumer reporting agency or its affiliate, the person must not disclose that information to any other person, except as necessary to carry out the purpose for which the information was initially disclosed, or as otherwise permitted by statute, regulation, or order.

§ 334.32 Sharing medical information with affiliates.

(a) *Scope.* This section applies to State banks insured by the FDIC (other than members of the Federal Reserve System) and insured State branches of foreign banks.

(b) *In general.* The exclusions from the term ''consumer report'' in section 603(d)(2) of the Act that allow the sharing of information with affiliates do not apply if a person described in paragraph (a) of this section communicates to an affiliate—

(1) Medical information;

(2) An individualized list or description based on the payment transactions of the consumer for medical products or services; or

(3) An aggregate list of identified consumers based on payment transactions for medical products or services.

(c) *Exceptions.* A person described in paragraph (a) of this section may rely on the exclusions from the term ''consumer report'' in section 603(d)(2) of the Act to communicate the information in paragraph (b) of this section to an affiliate—

(1) In connection with the business of insurance or annuities (including the activities described in section 18B of the model Privacy of Consumer Financial and Health Information Regulation issued by the National Association of Insurance Commissioners, as in effect on January 1, 2003);

(2) For any purpose permitted without authorization under the regulations promulgated by the Department of Health and Human Services pursuant to the Health Insurance Portability and Accountability Act of 1996 (HIPAA);

(3) For any purpose referred to in section 1179 of HIPAA;

(4) For any purpose described in section 502(e) of the Gramm-Leach-Bliley Act;

(5) In connection with a determination of the consumer's eligibility, or continued eligibility, for credit consistent with § 334.30; or

(6) As otherwise permitted by order of the FDIC.

Office of Thrift Supervision

12 CFR Chapter V.

Authority and Issuance

■ For the reasons set forth in the joint preamble, the Office of Thrift Supervision amends chapter V of title 12 of the Code of Federal Regulations as follows:

PART 571—FAIR CREDIT REPORTING

■ 1. The authority citation for part 571 is revised to read as follows:

Authority: 12 U.S.C. 1462a, 1463, 1464, 1467a, 1828, 1831p–1, and 1881–1884; 15 U.S.C. 1681b, 1681s, and 1681w; 15 U.S.C. 6801 and 6805(b)(1).

Subpart A—General Provisions

■ 2. Revise §571.1(b)(2) to read as follows:

§ 571.1 Purpose and Scope.

* * * * *

(b) * * *

(2) *Scope in general.* Except as otherwise provided in this part, this part applies to savings associations whose deposits are insured by the Federal Deposit Insurance Corporation (and Federal savings association operating subsidiaries in accordance with § 559.3(h)(1) of this chapter).

■ 3. Add §571.2 to read as follows:

§ 571.2 Examples.

The examples in this part are not exclusive. Compliance with an example, to the extent applicable, constitutes compliance with this part. Examples in a paragraph illustrate only the issue described in the paragraph and do not illustrate any other issue that may arise in this part.

■ 4. Amend §571.3 by revising the introductory text and paragraphs (a) through (n) to read as follows:

§ 571.3 Definitions.

As used in this part, unless the context requires otherwise:

(a) *Act* means the Fair Credit Reporting Act (15 U.S.C. 1681 *et seq.*).

(b) *Affiliate* means any company that is related by common ownership or common corporate control with another company.

(c) [Reserved]

(d) *Company* means any corporation, limited liability company, business trust, general or limited partnership, association, or similar organization.

(e) *Consumer* means an individual.

(f)–(h) [Reserved]

(i) *Common ownership or common corporate control* means a relationship between two companies under which:

(1) One company has, with respect to the other company:

(i) Ownership, control, or power to vote 25 percent or more of the outstanding shares of any class of voting security of a company, directly or indirectly, or acting through one or more other persons;

(ii) Control in any manner over the election of a majority of the directors, trustees, or general partners (or individuals exercising similar functions) of a company; or

(iii) The power to exercise, directly or indirectly, a controlling influence over the management or policies of a company, as the OTS determines; or

(2) Any other person has, with respect to both companies, a relationship described in paragraphs (i)(1)(i)–(i)(1)(iii) of this section.

(j) [Reserved]

(k) *Medical information* means:

(1) Information or data, whether oral or recorded, in any form or medium, created by or derived from a health care provider or the consumer, that relates to—

(i) The past, present, or future physical, mental, or behavioral health or condition of an individual;

(ii) The provision of health care to an individual; or

(iii) The payment for the provision of health care to an individual.

(2) The term does not include:

(i) The age or gender of a consumer;

(ii) Demographic information about the consumer, including a consumer's residence address or e-mail address;

(iii) Any other information about a consumer that does not relate to the physical, mental, or behavioral health or condition of a consumer, including the existence or value of any insurance policy; or

(iv) Information that does not identify a specific consumer.

(l) *Person* means any individual, partnership, corporation, trust, estate

cooperative, association, government or governmental subdivision or agency, or other entity.

(m)–(n) [Reserved]

* * * * *

■ 5. Add subpart D to part 571 to read as follows:

Subpart D—Medical Information

§ 571.30 Obtaining or using medical information in connection with a determination of eligibility for credit.

(a) *Scope.* This section applies to:

(1) Any of the following that participates as a creditor in a transaction—

(i) A savings association;

(ii) A subsidiary owned in whole or in part by a savings association;

(iii) A savings and loan holding company;

(iv) A subsidiary of a savings and loan holding company other than a bank or subsidiary of a bank; or

(v) A service corporation owned in whole or in part by a savings association; or

(2) Any other person that participates as a creditor in a transaction involving a person described in paragraph (a)(1) of this section.

(b) *General prohibition on obtaining or using medical information.* (1) *In general.* A creditor may not obtain or use medical information pertaining to a consumer in connection with any determination of the consumer's eligibility, or continued eligibility, for credit, except as provided in this section.

(2) *Definitions.* (i) *Credit* has the same meaning as in section 702 of the Equal Credit Opportunity Act, 15 U.S.C. 1691a.

(ii) *Creditor* has the same meaning as in section 702 of the Equal Credit Opportunity Act, 15 U.S.C. 1691a.

(iii) *Eligibility, or continued eligibility, for credit* means the consumer's qualification or fitness to receive, or continue to receive, credit, including the terms on which credit is offered. The term does not include:

(A) Any determination of the consumer's qualification or fitness for employment, insurance (other than a credit insurance product), or other non-credit products or services;

(B) Authorizing, processing, or documenting a payment or transaction on behalf of the consumer in a manner that does not involve a determination of the consumer's eligibility, or continued eligibility, for credit; or

(C) Maintaining or servicing the consumer's account in a manner that does not involve a determination of the consumer's eligibility, or continued eligibility, for credit.

(c) *Rule of construction for obtaining and using unsolicited medical information.* (1) *In general.* A creditor does not obtain medical information in violation of the prohibition if it receives medical information pertaining to a consumer in connection with any determination of the consumer's eligibility, or continued eligibility, for credit without specifically requesting medical information.

(2) *Use of unsolicited medical information.* A creditor that receives unsolicited medical information in the manner described in paragraph (c)(1) of this section may use that information in connection with any determination of the consumer's eligibility, or continued eligibility, for credit to the extent the creditor can rely on at least one of the exceptions in § 571.30(d) or (e).

(3) *Examples.* A creditor does not obtain medical information in violation of the prohibition if, for example:

(i) In response to a general question regarding a consumer's debts or expenses, the creditor receives information that the consumer owes a debt to a hospital;

(ii) In a conversation with the creditor's loan officer, the consumer informs the creditor that the consumer has a particular medical condition; or

(iii) In connection with a consumer's application for an extension of credit, the creditor requests a consumer report from a consumer reporting agency and receives medical information in the consumer report furnished by the agency even though the creditor did not specifically request medical information from the consumer reporting agency.

(d) *Financial information exception for obtaining and using medical information.* (1) *In general.* A creditor may obtain and use medical information pertaining to a consumer in connection with any determination of the consumer's eligibility, or continued eligibility, for credit so long as:

(i) The information is the type of information routinely used in making credit eligibility determinations, such as information relating to debts, expenses, income, benefits, assets, collateral, or the purpose of the loan, including the use of proceeds;

(ii) The creditor uses the medical information in a manner and to an extent that is no less favorable than it would use comparable information that is not medical information in a credit transaction; and

(iii) The creditor does not take the consumer's physical, mental, or behavioral health, condition or history, type of treatment, or prognosis into account as part of any such determination.

(2) *Examples.* (i) *Examples of the types of information routinely used in making credit eligibility determinations.* Paragraph (d)(1)(i) of this section permits a creditor, for example, to obtain and use information about:

(A) The dollar amount, repayment terms, repayment history, and similar information regarding medical debts to calculate, measure, or verify the repayment ability of the consumer, the use of proceeds, or the terms for granting credit;

(B) The value, condition, and lien status of a medical device that may serve as collateral to secure a loan;

(C) The dollar amount and continued eligibility for disability income or benefits related to health or a medical condition that is relied on as a source of repayment; or

(D) The identity of creditors to whom outstanding medical debts are owed in connection with an application for credit, including but not limited to, a transaction involving the consolidation of medical debts.

(ii) *Examples of uses of medical information consistent with the exception.* (A) A consumer includes on an application for credit information about two $20,000 debts. One debt is to a hospital; the other debt is to a retailer. The creditor contacts the hospital and the retailer to verify the amount and payment status of the debts. The creditor learns that both debts are more than 90 days past due. Any two debts of this size that are more than 90 days past due would disqualify the consumer under the creditor's established underwriting criteria. The creditor denies the application on the basis that the consumer has a poor repayment history on outstanding debts. The creditor has used medical information in a manner and to an extent no less favorable than it would use comparable non-medical information.

(B) A consumer indicates on an application for a $200,000 mortgage loan that she receives $15,000 in long-term disability income each year from her former employer and has no other income. Annual income of $15,000, regardless of source, would not be sufficient to support the requested amount of credit. The creditor denies the application on the basis that the projected debt-to-income ratio of the consumer does not meet the creditor's underwriting criteria. The creditor has used medical information in a manner and to an extent that is no less favorable than it would use comparable non-medical information.

(C) A consumer includes on an application for a $10,000 home equity loan that he has a $50,000 debt to a

medical facility that specializes in treating a potentially terminal disease. The creditor contacts the medical facility to verify the debt and obtain the repayment history and current status of the loan. The creditor learns that the debt is current. The applicant meets the income and other requirements of the creditor's underwriting guidelines. The creditor grants the application. The creditor has used medical information in accordance with the exception.

(iii) *Examples of uses of medical information inconsistent with the exception.* (A) A consumer applies for $25,000 of credit and includes on the application information about a $50,000 debt to a hospital. The creditor contacts the hospital to verify the amount and payment status of the debt, and learns that the debt is current and that the consumer has no delinquencies in her repayment history. If the existing debt were instead owed to a retail department store, the creditor would approve the application and extend credit based on the amount and repayment history of the outstanding debt. The creditor, however, denies the application because the consumer is indebted to a hospital. The creditor has used medical information, here the identity of the medical creditor, in a manner and to an extent that is less favorable than it would use comparable non-medical information.

(B) A consumer meets with a loan officer of a creditor to apply for a mortgage loan. While filling out the loan application, the consumer informs the loan officer orally that she has a potentially terminal disease. The consumer meets the creditor's established requirements for the requested mortgage loan. The loan officer recommends to the credit committee that the consumer be denied credit because the consumer has that disease. The credit committee follows the loan officer's recommendation and denies the application because the consumer has a potentially terminal disease. The creditor has used medical information in a manner inconsistent with the exception by taking into account the consumer's physical, mental, or behavioral health, condition, or history, type of treatment, or prognosis as part of a determination of eligibility or continued eligibility for credit.

(C) A consumer who has an apparent medical condition, such as a consumer who uses a wheelchair or an oxygen tank, meets with a loan officer to apply for a home equity loan. The consumer meets the creditor's established requirements for the requested home equity loan and the creditor typically does not require consumers to obtain a debt cancellation contract, debt suspension agreement, or credit insurance product in connection with such loans. However, based on the consumer's apparent medical condition, the loan officer recommends to the credit committee that credit be extended to the consumer only if the consumer obtains a debt cancellation contract, debt suspension agreement, or credit insurance product. The credit committee agrees with the loan officer's recommendation. The loan officer informs the consumer that the consumer must obtain a debt cancellation contract, debt suspension agreement, or credit insurance product to qualify for the loan. The consumer obtains one of these products from a third party and the creditor approves the loan. The creditor has used medical information in a manner inconsistent with the exception by taking into account the consumer's physical, mental, or behavioral health, condition, or history, type of treatment, or prognosis in setting conditions on the consumer's eligibility for credit.

(e) *Specific exceptions for obtaining and using medical information.* (1) *In general.* A creditor may obtain and use medical information pertaining to a consumer in connection with any determination of the consumer's eligibility, or continued eligibility, for credit—

(i) To determine whether the use of a power of attorney or legal representative that is triggered by a medical event or condition is necessary and appropriate or whether the consumer has the legal capacity to contract when a person seeks to exercise a power of attorney or act as legal representative for a consumer based on an asserted medical event or condition;

(ii) To comply with applicable requirements of local, State, or Federal laws;

(iii) To determine, at the consumer's request, whether the consumer qualifies for a legally permissible special credit program or credit-related assistance program that is—

(A) Designed to meet the special needs of consumers with medical conditions; and

(B) Established and administered pursuant to a written plan that—

(*1*) Identifies the class of persons that the program is designed to benefit; and

(*2*) Sets forth the procedures and standards for extending credit or providing other credit-related assistance under the program.

(iv) To the extent necessary for purposes of fraud prevention or detection;

(v) In the case of credit for the purpose of financing medical products or services, to determine and verify the medical purpose of a loan and the use of proceeds;

(vi) Consistent with safe and sound practices, if the consumer or the consumer's legal representative specifically requests that the creditor use medical information in determining the consumer's eligibility, or continued eligibility, for credit, to accommodate the consumer's particular circumstances, and such request is documented by the creditor;

(vii) Consistent with safe and sound practices, to determine whether the provisions of a forbearance practice or program that is triggered by a medical event or condition apply to a consumer;

(viii) To determine the consumer's eligibility for, the triggering of, or the reactivation of a debt cancellation contract or debt suspension agreement if a medical condition or event is a triggering event for the provision of benefits under the contract or agreement; or

(ix) To determine the consumer's eligibility for, the triggering of, or the reactivation of a credit insurance product if a medical condition or event is a triggering event for the provision of benefits under the product.

(2) *Example of determining eligibility for a special credit program or credit assistance program.* A not-for-profit organization establishes a credit assistance program pursuant to a written plan that is designed to assist disabled veterans in purchasing homes by subsidizing the down payment for the home purchase mortgage loans of qualifying veterans. The organization works through mortgage lenders and requires mortgage lenders to obtain medical information about the disability of any consumer that seeks to qualify for the program, use that information to verify the consumer's eligibility for the program, and forward that information to the organization. A consumer who is a veteran applies to a creditor for a home purchase mortgage loan. The creditor informs the consumer about the credit assistance program for disabled veterans and the consumer seeks to qualify for the program. Assuming that the program complies with all applicable law, including applicable fair lending laws, the creditor may obtain and use medical information about the medical condition and disability, if any, of the consumer to determine whether the consumer qualifies for the credit assistance program.

(3) *Examples of verifying the medical purpose of the loan or the use of proceeds.* (i) If a consumer applies for

$10,000 of credit for the purpose of financing vision correction surgery, the creditor may verify with the surgeon that the procedure will be performed. If the surgeon reports that surgery will not be performed on the consumer, the creditor may use that medical information to deny the consumer's application for credit, because the loan would not be used for the stated purpose.

(ii) If a consumer applies for $10,000 of credit for the purpose of financing cosmetic surgery, the creditor may confirm the cost of the procedure with the surgeon. If the surgeon reports that the cost of the procedure is $5,000, the creditor may use that medical information to offer the consumer only $5,000 of credit.

(iii) A creditor has an established medical loan program for financing particular elective surgical procedures. The creditor receives a loan application from a consumer requesting $10,000 of credit under the established loan program for an elective surgical procedure. The consumer indicates on the application that the purpose of the loan is to finance an elective surgical procedure not eligible for funding under the guidelines of the established loan program. The creditor may deny the consumer's application because the purpose of the loan is not for a particular procedure funded by the established loan program.

(4) *Examples of obtaining and using medical information at the request of the consumer.* (i) If a consumer applies for a loan and specifically requests that the creditor consider the consumer's medical disability at the relevant time as an explanation for adverse payment history information in his credit report, the creditor may consider such medical information in evaluating the consumer's willingness and ability to repay the requested loan to accommodate the consumer's particular circumstances, consistent with safe and sound practices. The creditor may also decline to consider such medical information to accommodate the consumer, but may evaluate the consumer's application in accordance with its otherwise applicable underwriting criteria. The creditor may not deny the consumer's application or otherwise treat the consumer less favorably because the consumer specifically requested a medical accommodation, if the creditor would have extended the credit or treated the consumer more favorably under the creditor's otherwise applicable underwriting criteria.

(ii) If a consumer applies for a loan by telephone and explains that his income has been and will continue to be interrupted on account of a medical condition and that he expects to repay the loan by liquidating assets, the creditor may, but is not required to, evaluate the application using the sale of assets as the primary source of repayment, consistent with safe and sound practices, provided that the creditor documents the consumer's request by recording the oral conversation or making a notation of the request in the consumer's file.

(iii) If a consumer applies for a loan and the application form provides a space where the consumer may provide any other information or special circumstances, whether medical or non-medical, that the consumer would like the creditor to consider in evaluating the consumer's application, the creditor may use medical information provided by the consumer in that space on that application to accommodate the consumer's application for credit, consistent with safe and sound practices, or may disregard that information.

(iv) If a consumer specifically requests that the creditor use medical information in determining the consumer's eligibility, or continued eligibility, for credit and provides the creditor with medical information for that purpose, and the creditor determines that it needs additional information regarding the consumer's circumstances, the creditor may request, obtain, and use additional medical information about the consumer as necessary to verify the information provided by the consumer or to determine whether to make an accommodation for the consumer. The consumer may decline to provide additional information, withdraw the request for an accommodation, and have the application considered under the creditor's otherwise applicable underwriting criteria.

(v) If a consumer completes and signs a credit application that is not for medical purpose credit and the application contains boilerplate language that routinely requests medical information from the consumer or that indicates that by applying for credit the consumer authorizes or consents to the creditor obtaining and using medical information in connection with a determination of the consumer's eligibility, or continued eligibility, for credit, the consumer has not specifically requested that the creditor obtain and use medical information to accommodate the consumer's particular circumstances.

(5) *Example of a forbearance practice or program.* After an appropriate safety and soundness review, a creditor institutes a program that allows consumers who are or will be hospitalized to defer payments as needed for up to three months, without penalty, if the credit account has been open for more than one year and has not previously been in default, and the consumer provides confirming documentation at an appropriate time. A consumer is hospitalized and does not pay her bill for a particular month. This consumer has had a credit account with the creditor for more than one year and has not previously been in default. The creditor attempts to contact the consumer and speaks with the consumer's spouse, who is not the consumer's legal representative. The spouse informs the creditor that the consumer is hospitalized and is unable to pay the bill at that time. The creditor defers payments for up to three months, without penalty, for the hospitalized consumer and sends the consumer a letter confirming this practice and the date on which the next payment will be due.

§ 571.31 Limits on redisclosure of information.

(a) *Scope.* This section applies to savings associations and federal savings association operating subsidiaries.

(b) *Limits on redisclosure.* If a person described in paragraph (a) of this section receives medical information about a consumer from a consumer reporting agency or its affiliate, the person must not disclose that information to any other person, except as necessary to carry out the purpose for which the information was initially disclosed, or as otherwise permitted by statute, regulation, or order.

§ 571.32 Sharing medical information with affiliates.

(a) *Scope.* This section applies to savings associations and Federal savings association operating subsidiaries.

(b) *In general.* The exclusions from the term ''consumer report'' in section 603(d)(2) of the Act that allow the sharing of information with affiliates do not apply if a person described in paragraph (a) of this section communicates to an affiliate—

(1) Medical information;

(2) An individualized list or description based on the payment transactions of the consumer for medical products or services; or

(3) An aggregate list of identified consumers based on payment transactions for medical products or services.

(c) *Exceptions.* A person described in paragraph (a) of this section may rely on

the exclusions from the term ''consumer report'' in section 603(d)(2) of the Act to communicate the information in paragraph (b) of this section to an affiliate—

(1) In connection with the business of insurance or annuities (including the activities described in section 18B of the model Privacy of Consumer Financial and Health Information Regulation issued by the National Association of Insurance Commissioners, as in effect on January 1, 2003);

(2) For any purpose permitted without authorization under the regulations promulgated by the Department of Health and Human Services pursuant to the Health Insurance Portability and Accountability Act of 1996 (HIPAA);

(3) For any purpose referred to in section 1179 of HIPAA;

(4) For any purpose described in section 502(e) of the Gramm-Leach-Bliley Act;

(5) In connection with a determination of the consumer's eligibility, or continued eligibility, for credit consistent with § 571.30; or

(6) As otherwise permitted by order of the OTS.

National Credit Union Administration

■ For the reasons set out in the preamble, 12 CFR chapter VII is amended as follows:

PART 717—FAIR CREDIT REPORTING

■ 1. Revise the authority citation for part 717 to read as follows:

Authority: 15 U.S.C. 1681a, 1681b, 1681s, 1681w, 6801 and 6805.

■ 2. Amend part 717 by revising subpart A to read as follows:

Subpart A—General Provisions

Sec.
717.1 Purpose.
717.2 Examples.
717.3 Definitions.

Subpart A—General Provisions

§ 717.1 Purpose.

(a) *Purpose.* The purpose of this part is to establish standards for Federal credit unions regarding consumer report information. In addition, the purpose of this part is to specify the extent to which Federal credit unions may obtain, use or share certain information. This part also contains a number of measures Federal credit unions must take to combat consumer fraud and related crimes, including identity theft.

(b) [Reserved]

§ 717.2 Examples.

The examples in this part are not exclusive. Compliance with an example, to the extent applicable, constitutes compliance with this part. Examples in a paragraph illustrate only the issue described in the paragraph and do not illustrate any other issue that may arise in this part.

§ 717.3 Definitions.

As used in this part, unless the context requires otherwise:

(a) *Act* means the Fair Credit Reporting Act (15 U.S.C. 1681 *et seq.*).

(b) *Affiliate* means any company that is related by common ownership or common corporate control with another company. For example, an affiliate of a Federal credit union is a credit union service corporation (CUSO), as provided in 12 CFR part 712, that is controlled by the Federal credit union.

(c) [Reserved]

(d) *Company* means any corporation, limited liability company, business trust, general or limited partnership, association, or similar organization.

(e) *Consumer* means an individual.

(f) [Reserved]

(g) [Reserved]

(h) [Reserved]

(i) *Common ownership or common corporate control* means a relationship between two companies under which:

(1) One company has, with respect to the other company:

(i) Ownership, control, or power to vote 25 percent or more of the outstanding shares of any class of voting security of a company, directly or indirectly, or acting through one or more other persons;

(ii) Control in any manner over the election of a majority of the directors, trustees, or general partners (or individuals exercising similar functions) of a company; or

(iii) The power to exercise, directly or indirectly, a controlling influence over the management or policies of a company, as the NCUA determines; or

(iv) Example. NCUA will presume a credit union has a controlling influence over the management or policies of a CUSO, if the CUSO is 67% owned by credit unions.

(2) Any other person has, with respect to both companies, a relationship described in paragraphs (i)(1)(i)–(i)(1)(iii) of this section.

(j) [Reserved]

(k) *Medical information* means:

(l) Information or data, whether oral or recorded, in any form or medium, created by or derived from a health care provider or the consumer, that relates to—

(i) The past, present, or future physical, mental, or behavioral health or condition of an individual;

(ii) The provision of health care to an individual; or

(iii) The payment for the provision of health care to an individual.

(2) The term does not include:

(i) The age or gender of a consumer;

(ii) Demographic information about the consumer, including a consumer's residence address or e-mail address;

(iii) Any other information about a consumer that does not relate to the physical, mental, or behavioral health or condition of a consumer, including the existence or value of any insurance policy; or

(iv) Information that does not identify a specific consumer.

(l) *Person* means any individual, partnership, corporation, trust, estate cooperative, association, government or governmental subdivision or agency, or other entity.

■ 3. Subpart D is added to part 717 to read as follows:

Subpart D—Medical Information

§ 717.30 Obtaining or using medical information in connection with a determination of eligibility for credit.

(a) *Scope.* This section applies to:

(1) A Federal credit union that participates as a creditor in a transaction; or

(2) Any other person that participates as a creditor in a transaction involving a person described in paragraph (1).

(b) *General prohibition on obtaining or using medical information.* (1) *In general.* A creditor may not obtain or use medical information pertaining to a consumer in connection with any determination of the consumer's eligibility, or continued eligibility, for credit, except as provided in this section.

(2) *Definitions.* (i) *Credit* has the same meaning as in section 702 of the Equal Credit Opportunity Act, 15 U.S.C. 1691a.

(ii) *Creditor* has the same meaning as in section 702 of the Equal Credit Opportunity Act, 15 U.S.C. 1691a.

(iii) *Eligibility, or continued eligibility, for credit* means the consumer's qualification or fitness to receive, or continue to receive, credit, including the terms on which credit is offered. The term does not include:

(A) Any determination of the consumer's qualification or fitness for employment, insurance (other than a credit insurance product), or other non-credit products or services;

(B) Authorizing, processing, or documenting a payment or transaction on behalf of the consumer in a manner that does not involve a determination of the consumer's eligibility, or continued eligibility, for credit; or

(C) Maintaining or servicing the consumer's account in a manner that

does not involve a determination of the consumer's eligibility, or continued eligibility, for credit.

(c) *Rule of construction for obtaining and using unsolicited medical information.* (1) *In general.* A creditor does not obtain medical information in violation of the prohibition if it receives medical information pertaining to a consumer in connection with any determination of the consumer's eligibility, or continued eligibility, for credit without specifically requesting medical information.

(2) *Use of unsolicited medical information.* A creditor that receives unsolicited medical information in the manner described in paragraph (1) may use that information in connection with any determination of the consumer's eligibility, or continued eligibility, for credit to the extent the creditor can rely on at least one of the exceptions in § 717.30(d) or (e).

(3) *Examples.* A creditor does not obtain medical information in violation of the prohibition if, for example:

(i) In response to a general question regarding a consumer's debts or expenses, the creditor receives information that the consumer owes a debt to a hospital.

(ii) In a conversation with the creditor's loan officer, the consumer informs the creditor that the consumer has a particular medical condition.

(iii) In connection with a consumer's application for an extension of credit, the creditor requests a consumer report from a consumer reporting agency and receives medical information in the consumer report furnished by the agency even though the creditor did not specifically request medical information from the consumer reporting agency.

(d) *Financial information exception for obtaining and using medical information.*

(1) *In general.* A creditor may obtain and use medical information pertaining to a consumer in connection with any determination of the consumer's eligibility, or continued eligibility, for credit so long as:

(i) The information is the type of information routinely used in making credit eligibility determinations, such as information relating to debts, expenses, income, benefits, assets, collateral, or the purpose of the loan, including the use of proceeds;

(ii) The creditor uses the medical information in a manner and to an extent that is no less favorable than it would use comparable information that is not medical information in a credit transaction; and

(iii) The creditor does not take the consumer's physical, mental, or behavioral health, condition or history, type of treatment, or prognosis into account as part of any such determination.

(2) *Examples.* (i) *Examples of the types of information routinely used in making credit eligibility determinations.* Paragraph (d)(1)(i) of this section permits a creditor, for example, to obtain and use information about:

(A) The dollar amount, repayment terms, repayment history, and similar information regarding medical debts to calculate, measure, or verify the repayment ability of the consumer, the use of proceeds, or the terms for granting credit;

(B) The value, condition, and lien status of a medical device that may serve as collateral to secure a loan;

(C) The dollar amount and continued eligibility for disability income or benefits related to health or a medical condition that is relied on as a source of repayment; or

(D) The identity of creditors to whom outstanding medical debts are owed in connection with an application for credit, including but not limited to, a transaction involving the consolidation of medical debts.

(ii) *Examples of uses of medical information consistent with the exception.* (A) A consumer includes on an application for credit information about two $20,000 debts. One debt is to a hospital; the other debt is to a retailer. The creditor contacts the hospital and the retailer to verify the amount and payment status of the debts. The creditor learns that both debts are more than 90 days past due. Any two debts of this size that are more than 90 days past due would disqualify the consumer under the creditor's established underwriting criteria. The creditor denies the application on the basis that the consumer has a poor repayment history on outstanding debts. The creditor has used medical information in a manner and to an extent no less favorable than it would use comparable non-medical information.

(B) A consumer indicates on an application for a $200,000 mortgage loan that she receives $15,000 in long-term disability income each year from her former employer and has no other income. Annual income of $15,000, regardless of source, would not be sufficient to support the requested amount of credit. The creditor denies the application on the basis that the projected debt-to-income ratio of the consumer does not meet the creditor's underwriting criteria. The creditor has used medical information in a manner and to an extent that is no less favorable than it would use comparable non-medical information.

(C) A consumer includes on an application for a $10,000 home equity loan that he has a $50,000 debt to a medical facility that specializes in treating a potentially terminal disease. The creditor contacts the medical facility to verify the debt and obtain the repayment history and current status of the loan. The creditor learns that the debt is current. The applicant meets the income and other requirements of the creditor's underwriting guidelines. The creditor grants the application. The creditor has used medical information in accordance with the exception.

(iii) *Examples of uses of medical information inconsistent with the exception.* (A) A consumer applies for $25,000 of credit and includes on the application information about a $50,000 debt to a hospital. The creditor contacts the hospital to verify the amount and payment status of the debt, and learns that the debt is current and that the consumer has no delinquencies in her repayment history. If the existing debt were instead owed to a retail department store, the creditor would approve the application and extend credit based on the amount and repayment history of the outstanding debt. The creditor, however, denies the application because the consumer is indebted to a hospital. The creditor has used medical information, here the identity of the medical creditor, in a manner and to an extent that is less favorable than it would use comparable non-medical information.

(B) A consumer meets with a loan officer of a creditor to apply for a mortgage loan. While filling out the loan application, the consumer informs the loan officer orally that she has a potentially terminal disease. The consumer meets the creditor's established requirements for the requested mortgage loan. The loan officer recommends to the credit committee that the consumer be denied credit because the consumer has that disease. The credit committee follows the loan officer's recommendation and denies the application because the consumer has a potentially terminal disease. The creditor has used medical information in a manner inconsistent with the exception by taking into account the consumer's physical, mental, or behavioral health, condition, or history, type of treatment, or prognosis as part of a determination of eligibility or continued eligibility for credit.

(C) A consumer who has an apparent medical condition, such as a consumer who uses a wheelchair or an oxygen

tank, meets with a loan officer to apply for a home equity loan. The consumer meets the creditor's established requirements for the requested home equity loan and the creditor typically does not require consumers to obtain a debt cancellation contract, debt suspension agreement, or credit insurance product in connection with such loans. However, based on the consumer's apparent medical condition, the loan officer recommends to the credit committee that credit be extended to the consumer only if the consumer obtains a debt cancellation contract, debt suspension agreement, or credit insurance product. The credit committee agrees with the loan officer's recommendation. The loan officer informs the consumer that the consumer must obtain a debt cancellation contract, debt suspension agreement, or credit insurance product to qualify for the loan. The consumer obtains one of these products from a third party and the creditor approves the loan. The creditor has used medical information in a manner inconsistent with the exception by taking into account the consumer's physical, mental, or behavioral health, condition, or history, type of treatment, or prognosis in setting conditions on the consumer's eligibility for credit.

(e) *Specific exceptions for obtaining and using medical information.* (1) *In general.* A creditor may obtain and use medical information pertaining to a consumer in connection with any determination of the consumer's eligibility, or continued eligibility, for credit—

(i) To determine whether the use of a power of attorney or legal representative that is triggered by a medical event or condition is necessary and appropriate or whether the consumer has the legal capacity to contract when a person seeks to exercise a power of attorney or act as legal representative for a consumer based on an asserted medical event or condition;

(ii) To comply with applicable requirements of local, State, or Federal laws;

(iii) To determine, at the consumer's request, whether the consumer qualifies for a legally permissible special credit program or credit-related assistance program that is—

(A) Designed to meet the special needs of consumers with medical conditions; and

(B) Established and administered pursuant to a written plan that—

(*1*) Identifies the class of persons that the program is designed to benefit; and

(*2*) Sets forth the procedures and standards for extending credit or providing other credit-related assistance under the program.

(iv) To the extent necessary for purposes of fraud prevention or detection;

(v) In the case of credit for the purpose of financing medical products or services, to determine and verify the medical purpose of a loan and the use of proceeds;

(vi) Consistent with safe and sound practices, if the consumer or the consumer's legal representative specifically requests that the creditor use medical information in determining the consumer's eligibility, or continued eligibility, for credit, to accommodate the consumer's particular circumstances, and such request is documented by the creditor;

(vii) Consistent with safe and sound practices, to determine whether the provisions of a forbearance practice or program that is triggered by a medical event or condition apply to a consumer;

(viii) To determine the consumer's eligibility for, the triggering of, or the reactivation of a debt cancellation contract or debt suspension agreement if a medical condition or event is a triggering event for the provision of benefits under the contract or agreement; or

(ix) To determine the consumer's eligibility for, the triggering of, or the reactivation of a credit insurance product if a medical condition or event is a triggering event for the provision of benefits under the product.

(2) *Example of determining eligibility for a special credit program or credit assistance program.* A not-for-profit organization establishes a credit assistance program pursuant to a written plan that is designed to assist disabled veterans in purchasing homes by subsidizing the down payment for the home purchase mortgage loans of qualifying veterans. The organization works through mortgage lenders and requires mortgage lenders to obtain medical information about the disability of any consumer that seeks to qualify for the program, use that information to verify the consumer's eligibility for the program, and forward that information to the organization. A consumer who is a veteran applies to a creditor for a home purchase mortgage loan. The creditor informs the consumer about the credit assistance program for disabled veterans and the consumer seeks to qualify for the program. Assuming that the program complies with all applicable law, including applicable fair lending laws, the creditor may obtain and use medical information about the medical condition and disability, if any, of the consumer to determine whether the consumer qualifies for the credit assistance program.

(3) *Examples of verifying the medical purpose of the loan or the use of proceeds.* (i) If a consumer applies for $10,000 of credit for the purpose of financing vision correction surgery, the creditor may verify with the surgeon that the procedure will be performed. If the surgeon reports that surgery will not be performed on the consumer, the creditor may use that medical information to deny the consumer's application for credit, because the loan would not be used for the stated purpose.

(ii) If a consumer applies for $10,000 of credit for the purpose of financing cosmetic surgery, the creditor may confirm the cost of the procedure with the surgeon. If the surgeon reports that the cost of the procedure is $5,000, the creditor may use that medical information to offer the consumer only $5,000 of credit.

(iii) A creditor has an established medical loan program for financing particular elective surgical procedures. The creditor receives a loan application from a consumer requesting $10,000 of credit under the established loan program for an elective surgical procedure. The consumer indicates on the application that the purpose of the loan is to finance an elective surgical procedure not eligible for funding under the guidelines of the established loan program. The creditor may deny the consumer's application because the purpose of the loan is not for a particular procedure funded by the established loan program.

(4) *Examples of obtaining and using medical information at the request of the consumer.* (i) If a consumer applies for a loan and specifically requests that the creditor consider the consumer's medical disability at the relevant time as an explanation for adverse payment history information in his credit report, the creditor may consider such medical information in evaluating the consumer's willingness and ability to repay the requested loan to accommodate the consumer's particular circumstances, consistent with safe and sound practices. The creditor may also decline to consider such medical information to accommodate the consumer, but may evaluate the consumer's application in accordance with its otherwise applicable underwriting criteria. The creditor may not deny the consumer's application or otherwise treat the consumer less favorably because the consumer specifically requested a medical accommodation, if the creditor would have extended the credit or treated the

consumer more favorably under the creditor's otherwise applicable underwriting criteria.

(ii) If a consumer applies for a loan by telephone and explains that his income has been and will continue to be interrupted on account of a medical condition and that he expects to repay the loan by liquidating assets, the creditor may, but is not required to, evaluate the application using the sale of assets as the primary source of repayment, consistent with safe and sound practices, provided that the creditor documents the consumer's request by recording the oral conversation or making a notation of the request in the consumer's file.

(iii) If a consumer applies for a loan and the application form provides a space where the consumer may provide any other information or special circumstances, whether medical or non-medical, that the consumer would like the creditor to consider in evaluating the consumer's application, the creditor may use medical information provided by the consumer in that space on that application to accommodate the consumer's application for credit, consistent with safe and sound practices, or may disregard that information.

(iv) If a consumer specifically requests that the creditor use medical information in determining the consumer's eligibility, or continued eligibility, for credit and provides the creditor with medical information for that purpose, and the creditor determines that it needs additional information regarding the consumer's circumstances, the creditor may request, obtain, and use additional medical information about the consumer as necessary to verify the information provided by the consumer or to determine whether to make an accommodation for the consumer. The consumer may decline to provide additional information, withdraw the request for an accommodation, and have the application considered under the creditor's otherwise applicable underwriting criteria.

(v) If a consumer completes and signs a credit application that is not for medical purpose credit and the application contains boilerplate language that routinely requests medical information from the consumer or that indicates that by applying for credit the consumer authorizes or consents to the creditor obtaining and using medical information in connection with a determination of the consumer's eligibility, or continued eligibility, for credit, the consumer has not specifically requested that the creditor obtain and use medical information to accommodate the consumer's particular circumstances.

(5) *Example of a forbearance practice or program.* After an appropriate safety and soundness review, a creditor institutes a program that allows consumers who are or will be hospitalized to defer payments as needed for up to three months, without penalty, if the credit account has been open for more than one year and has not previously been in default, and the consumer provides confirming documentation at an appropriate time. A consumer is hospitalized and does not pay her bill for a particular month. This consumer has had a credit account with the creditor for more than one year and has not previously been in default. The creditor attempts to contact the consumer and speaks with the consumer's adult child, who is not the consumer's legal representative. The adult child informs the creditor that the consumer is hospitalized and is unable to pay the bill at that time. The creditor defers payments for up to three months, without penalty, for the hospitalized consumer and sends the consumer a letter confirming this practice and the date on which the next payment will be due.

§ 717.31 Limits on redisclosure of information.

(a) *Scope.* This section applies to Federal credit unions.

(b) *Limits on redisclosure.* If a Federal credit union receives medical information about a consumer from a consumer reporting agency or its affiliate, the person must not disclose that information to any other person, except as necessary to carry out the purpose for which the information was initially disclosed, or as otherwise permitted by statute, regulation, or order.

§ 717.32 Sharing medical information with affiliates.

(a) *Scope.* This section applies to Federal credit unions.

(b) *In general.* The exclusions from the term ''consumer report'' in section 603(d)(2) of the Act that allow the sharing of information with affiliates do not apply if a Federal credit union communicates to an affiliate—

(1) Medical information;

(2) An individualized list or description based on the payment transactions of the consumer for medical products or services; or

(3) An aggregate list of identified consumers based on payment transactions for medical products or services.

(c) *Exceptions.* A Federal credit union may rely on the exclusions from the term ''consumer report'' in section 603(d)(2) of the Act to communicate the information in paragraph (b) to an affiliate—

(1) In connection with the business of insurance or annuities (including the activities described in section 18B of the model Privacy of Consumer Financial and Health Information Regulation issued by the National Association of Insurance Commissioners, as in effect on January 1, 2003);

(2) For any purpose permitted without authorization under the regulations promulgated by the Department of Health and Human Services pursuant to the Health Insurance Portability and Accountability Act of 1996 (HIPAA);

(3) For any purpose referred to in section 1179 of HIPAA;

(4) For any purpose described in section 502(e) of the Gramm-Leach-Bliley Act;

(5) In connection with a determination of the consumer's eligibility, or continued eligibility, for credit consistent with § 717.30; or

(6) As otherwise permitted by order of the NCUA.

By order of the Board of Governors of the Federal Reserve System, June 2, 2005.

Jennifer J. Johnson,

Secretary of the Board.

Dated: May 25, 2005.

Julie L. Williams,

Acting Comptroller of the Currency.

Dated at Washington, DC, this 16th day of May, 2005.

By order of the Board of Directors.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

Dated: May 19, 2005.

By the Office of Thrift Supervision.

Richard M. Riccobono,

Acting Director.

By the National Credit Union Administration Board on June 1, 2005.

Mary F. Rupp,

Secretary of the Board.

[FR Doc. 05–11356 Filed 6–9–05; 8:45 am]

BILLING CODE 4810–33–P, 6210–01–P, 6714–10–P, 6720–01–P, 7535–01–P

Federal Register

Friday,
June 10, 2005

Part III

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 1020

Electronic Products; Performance Standard for Diagnostic X-Ray Systems and Their Major Components; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1020

[Docket No. 2001N–0275]

RIN 0910–AC34

Electronic Products; Performance Standard for Diagnostic X-Ray Systems and Their Major Components

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule to amend the Federal performance standard for diagnostic x-ray systems and their major components (the performance standard). The agency is taking this action to update the performance standard to account for changes in technology and use of radiographic and fluoroscopic x-ray systems and to fully utilize the International System of Units to describe radiation-related quantities and their units when used in the performance standard. For clarity and ease of understanding, FDA is republishing the complete contents, as amended, of three sections of the performance standard regulations and is amending a fourth section without republishing it in its entirety. This action is being taken under the Federal Food, Drug, and Cosmetic Act (the act), as amended by the Safe Medical Devices Act of 1990 (SMDA).

DATES: This rule is effective June 10, 2006.

FOR FURTHER INFORMATION CONTACT: Thomas B. Shope, Center for Devices and Radiological Health (HFZ–140), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–3314, ext. 132.

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I. Background

The SMDA (Public Law 101–629) transferred the provisions of the Radiation Control for Health and Safety Act of 1968 (RCHSA) (Public Law 90–602) from title III of the Public Health Service Act (PHS Act) (42 U.S.C. 201 *et seq.*) to chapter V of the act (21 U.S.C. 301 *et seq.*). Under the act, FDA administers an electronic product radiation control program to protect the public health and safety. As part of that program, FDA has authority to issue regulations prescribing radiation safety performance standards for electronic products, including diagnostic x-ray systems (sections 532 and 534 of the act (21 U.S.C. 360ii(a) and 360kk)).

The purpose of the performance standard for diagnostic x-ray systems is to improve the public health by reducing exposure to and the detriment associated with unnecessary ionizing radiation while assuring the clinical utility of the images produced.

In order for mandatory performance standards to continue to provide the intended public health protection, the standards must be modified when appropriate to reflect the changes in technology and product usage. When the performance standard was originally developed, the only means of producing a fluoroscopic image was either a screen of fluorescent material or an x-ray image intensifier tube. Therefore, the standard was written with these two types of image receptors in mind. A number of technological developments have been implemented for radiographic and fluoroscopic x-ray systems, such as solid-state x-ray imaging (SSXI) and new modes of image recording (e.g., digital recording to computer memory or other media). These developments have made the application of the current standard to systems incorporating these new technologies cumbersome and awkward. FDA is therefore amending the performance standard for diagnostic x-ray systems and their major components in §§ 1020.30, 1020.31, and 1020.32 (21 CFR 1020.30, 1020.31, and 1020.32) to address the recent changes in technology. In addition, we are amending § 1030.33(h) (21 CFR 1030.33(h)) to reflect the change in the quantity used to describe radiation.

These amendments will require that newly-manufactured x-ray systems include additional features that physicians may use to minimize x-ray exposures to patients. Advances in technology have made several of these new features feasible at minimal additional cost.

In the **Federal Register** of August 15, 1972 (37 FR 16461), FDA issued a final rule for the performance standard, which became effective on August 1, 1974. Since then, FDA has made several amendments to the performance

standard to incorporate new technology, to clarify misinterpreted provisions, or to incorporate additional requirements necessary to provide for adequate radiation safety of diagnostic x-ray systems. (See, e.g., amendments published on October 7, 1974 (39 FR 36008); February 25, 1977 (42 FR 10983); September 2, 1977 (42 FR 44230); November 8, 1977 (42 FR 58167); May 22, 1979 (44 FR 29653); August 24, 1979 (44 FR 49667); November 30, 1979 (44 FR 68822); April 25, 1980 (45 FR 27927); August 31, 1984 (49 FR 34698); May 3, 1993 (58 FR 26386); May 19, 1994 (59 FR 26402); and July 2, 1999 (64 FR 35924)).

In the **Federal Register** of December 11, 1997 (62 FR 65235), FDA issued an advance notice of proposed rulemaking (ANPRM) requesting comments on the proposed conceptual changes to the performance standard. The agency received 12 comments from State and local radiation control agencies, manufacturers, and a manufacturer organization. FDA considered these comments in developing the proposed amendments. In addition, the concepts embodied in the amendments were discussed on April 8, 1997, during a public meeting of the Technical Electronic Product Radiation Safety Standards Committee (TEPRSSC). TEPRSSC is a statutory advisory committee that FDA is required to consult before the agency may prescribe any electronic product performance standard under the act (21 U.S.C. 360kk(f)(1)(A)). The proposed amendments themselves were discussed in detail with the TEPRSSC during a public meeting held on September 23 and 24, 1998. At that meeting, TEPRSSC approved the content of the proposed amendments and concurred with their publication for public comment.

FDA proposed the amendments for public comment in the **Federal Register** of December 10, 2002 (67 FR 76056). Interested persons were given until April 9, 2003, to comment on the proposal. FDA received comments from 12 organizations and individuals in response to the proposed amendments. These comments were generally supportive of the proposed changes to the performance standard, although some expressed concern about specific aspects of some of the proposed amendments.

II. Highlights of the Final Rule

In this final rule, FDA is making a number of changes to the performance standard for diagnostic x-ray systems and their components, including the following:

- In § 1020.30 of the performance standard, the final rule makes the following changes:

Adds a number of new definitions to address new technologies and to further clarify the regulations. One notable amendment to the definitions is the addition of the terms *air kerma* and *kerma* to reflect a change in the quantity used to describe radiation emissions from diagnostic x-ray systems (§ 1020.30(b));

Requires manufacturers to provide users (e.g., physicians) with certain information regarding the new features of fluoroscopic systems in order to better protect their patients from unnecessary x-radiation exposure (§ 1020.30(h));

Requires additional warning label language designed to alert users and facility administrators to the need to properly maintain and calibrate their diagnostic x-ray systems (§ 1020.30(j)); and

Modifies existing beam quality requirements by increasing the required minimum half-value layer (HVL) values for radiographic and fluoroscopic equipment. This increase in HVL values will bring FDA requirements into agreement with the performance already provided by systems that are compliant with corresponding international standards. Therefore, manufacturers currently complying with the international standards should not be impacted by this change (§ 1020.30(m)).

- In § 1020.31 of the performance standard, which addresses radiographic x-ray equipment, the following changes are being made:

A number of minor, technical corrections to sections applicable to mammographic x-ray systems that were made necessary by an oversight that occurred when this performance standard was amended in July 1999 (§ 1020.31(f)(3) and (m)).

- The provisions in § 1020.32 pertain to fluoroscopic equipment. Key changes being made to this section of the performance standard include the following:

Amending the x-ray field limitation and alignment requirements to promote the addition of features designed to reduce the amount of radiation falling outside the visible area of the image receptor, thereby preventing unnecessary patient exposure (§ 1020.32(b));

Amending the requirement concerning maximum limits on entrance air kerma rates (AKR) in order to clarify the circumstances under which the maximum limits would apply (§ 1020.32(d) and (e));

Establishing a minimum source-skin distance requirement for certain small ''C-arm'' type fluoroscopic systems. FDA traditionally has granted variances from minimum source-skin distance requirements for small, portable C-arm systems when such systems were intended only for the limited use of imaging extremities. The amendment establishes the conditions under which variances have been granted as part of the standard and removes the need for manufacturers to continue to request variances of this type and makes explicit the requirements for these systems (§ 1020.32(g));

Requiring the incorporation of a feature that will continuously display the last fluoroscopic image taken prior to termination of exposure (last-image-hold feature). This permits the user to conveniently view fluoroscopic images without continuously irradiating the patient (§ 1020.32(j)); and

Requiring the incorporation of a feature that will display critical information to the fluoroscopist regarding patient irradiation, including the duration, rate (AKR), and amount (cumulative air kerma) of exposure (§ 1020.32(k));

- Section 1020.33 addresses computed tomography (CT) equipment. With regard to CT systems, the final rule makes the following changes:

Amends the requirements pertaining to beam-on and shutter status indicators to reflect the change in quantity used to describe x-radiation from exposure to air kerma. This modification does not alter the level of radiation protection provided by the existing standard (§ 1020.33(h)).

III. Summary and Analysis of Comments and FDA's Responses

A. General Comments

(Comment 1) FDA received 12 comments on the proposed amendments to the performance standard, many of which addressed multiple issues. In general tone and content all 12 individuals or organizations that commented supported the need for amendments and the approach proposed by FDA. A number of the comments provided suggestions or critiques regarding specific aspects of the proposed changes or suggested additional changes or additions for FDA consideration that were not part of the FDA proposal. The specific comments and FDA's responses will be discussed in the following paragraphs for each section of the performance standard.

Seven of the comments provided general comments that did not address specific proposed changes. Some of

them addressed the impact analysis or the estimate of the potential benefits that would likely result from the amendments. All seven comments were generally supportive of the changes proposed by FDA. Two comments suggested that the benefits of the proposed changes would be greater than estimated by FDA. One comment, from a State agency, suggested that the patient dose reductions would be greater than estimated by FDA, based on the State agency's experience with programs that have improved the information provided to facilities regarding patient radiation doses. Another comment suggested that the benefit of any dose reduction resulting from the amendments would greatly exceed FDA's estimates and criticized FDA for suggesting that the risk from x-ray radiation is much less than the comment believes it to be. Two of the comments complimented FDA on its analysis of the potential impact of the regulation.

(Response) We acknowledge and appreciate the supportive comments. This rule includes important modifications to the Federal performance standard for diagnostic x-ray systems to address recent changes in the technology and usage of radiographic and fluoroscopic x-ray systems. These modifications will help ensure that the performance standard will continue to protect and improve the public health by reducing exposure to unnecessary ionizing radiation while assuring the continued clinical utility of images produced where these new technologies are in use.

(Comment 2) Two comments questioned the need to apply several of the requirements to all fluoroscopic x-ray systems, noting that the benefit of the requirements such as for display of dose information and a last-image-hold feature would largely result from fluoroscopic equipment used for interventional procedures. At least five other comments explicitly supported application of the requirements to all fluoroscopic systems.

(Response) FDA notes that performance requirements must be tied to equipment characteristics and not to the potential manner in which the equipment may be used. Because interventional procedures may be performed using many types of fluoroscopic equipment, and because the added costs of the requirements are not expected to be overly burdensome, FDA has determined that the requirements should apply to all fluoroscopic equipment as proposed.

(Comment 3) Two comments supported the change in the quantity proposed for the description of radiation in the standard from exposure to air kerma. One of these comments was fairly general, while the other expressed specific support for the approach taken in the proposal that will maintain all of the various limits on radiation contained in different requirements of the standard at the same effective level as in the limits in the current standard where they were expressed using the quantity roentgen.

(Response) FDA believes that the radiation limits contained in the existing requirements remain appropriate. Although the change from exposure to air kerma will result in different numerical values that may no longer be integer numbers or multiples of 5 or 10 as was previously the case, the level of radiation protection will effectively be the same.

(Comment 4) FDA received comments in response to questions posed by the agency in the preamble of the proposed rule. FDA invited comments on several questions regarding approaches that could be taken to assure the radiation safety of fluoroscopic systems through performance requirements. These questions, which were not associated with specific proposed amendments, were intended to gather information that might guide FDA in considering any future modifications to the performance standard. Among the questions FDA presented for comment was whether there are any clinical situations that could require entrance AKRs greater than those currently permitted. FDA also invited comment on whether limits should be established for the entrance AKR at the entrance surface of the fluoroscopic image receptor and, if so, how these limits might be determined and established.

FDA received three comments in response to the questions about entrance air kerma rates. Two comments recommended that limits should not be established for the entrance air kerma rate at the entrance surface of the fluoroscopic image receptor. A third comment suggested that a mode of operation that would permit momentary imaging with entrance air kerma rates exceeding current limits should be considered if limits were to be established for the entrance air kerma rate at the entrance to the fluoroscopic image receptor. This comment also noted that any consideration of limits should involve the corresponding fluoroscopic image quality, and suggested that this is an area for further consideration by FDA in collaboration with interested parties. However, these comments did not make specific suggestions for requirements or provide data or evidence regarding such requirements.

(Response) FDA appreciates these suggestions. Although FDA has decided not to implement them at this time, FDA will involve interested parties in discussions about such requirements if modifications such as these are undertaken in the future.

(Comment 5) Two comments supported the need to modify the performance standard to address newly-evolving technologies. Although both comments agreed with FDA's proposed approach, they suggested that any future efforts to further address new technology with additional performance requirements, beyond the current proposed changes, would benefit from additional consultations between FDA and interested or affected parties. One of these comments suggested that consideration of further requirements to address additional characteristics of digital detectors or solid state x-ray imaging devices would benefit from interactive consultations with professional and scientific organizations. The other comment suggested that these areas could be addressed through the International Electrotechnical Commission's (IEC) standards development process.

(Response) FDA agrees with these suggestions and will encourage and facilitate such discussions should the future development of additional amendments be undertaken.

B. Comments on Proposed Changes to § 1020.30

1. Definitions (§ 1020.30(b))

As discussed in the preamble to the proposed rule, FDA proposed the inclusion of a number of new definitions in § 1020.30(b) to address new technologies and to further clarify the regulations. In addition to the changes to definitions proposed by FDA, a number of comments suggested modifications of additional, existing definitions or noted that new definitions were needed for clarity.

(Comment 6) One comment suggested that the definitions in the standard be harmonized to the extent possible with those used by the IEC.

(Response) FDA declines to make this change. The definitions in the U.S. standard were developed and finalized before the development of the IEC standards for x-ray equipment. Complete adoption of the IEC definitions would require FDA to overhaul the entire U.S. standard to bring it in line with the different structure and approach used in the IEC standards. In addition, the U.S. standard

reflects differences in common usage. For example, the IEC standard uses the term ''radioscopy'' instead of the term ''fluoroscopy'' as commonly used in the United States. For these reasons, FDA does not believe that such wholesale revisions are warranted at this time.

(Comment 7) FDA received a comment concerning the definition of attenuation block that noted that the current size specified is not large enough to accommodate the large x-ray field sizes used in conjunction with some current fluoroscopic image receptors that are significantly larger than earlier image receptors.

(Response) In response to this comment, FDA has modified the definition to indicate that an attenuation block with dimensions larger than currently specified is allowed. The new definition reads:

Attenuation block means a block or stack of type 1100 aluminum alloy or aluminum alloy having equivalent attenuation with dimensions 20 centimeters or larger by 20 centimeters or larger by 3.8 centimeters. When used, the attenuation block shall be large enough to intercept the entire x-ray beam.

(Comment 8) One comment suggested the need for clarification of what the term C-arm fluoroscope means as used in the standard.

(Response) FDA agrees that clarification would be useful and has included a new definition for this term in the final rule. The new definition reads:

C-arm fluoroscope means a fluoroscopic x-ray system in which the image receptor and x-ray tube housing assembly are connected or coordinated to maintain a spatial relationship. Such a system allows a change in the direction of the beam axis with respect to the patient without moving the patient.

Note that this definition will include some systems in which the x-ray tube and the fluoroscopic imaging assembly are not connected by a C-shaped mechanical connection. The distinguishing feature of a C-arm fluoroscope is the capability to change the orientation of the x-ray beam.

(Comment 9) In the preamble to the proposed rule, FDA noted that the word ''exposure'' is used in the standard with two different meanings. One comment suggested adding the second meaning of exposure to the definition for clarity.

(Response) FDA agrees with this comment. Accordingly, the definition of exposure is revised to read:

Exposure (X) means the quotient of dQ by dm, where dQ is the absolute value of the total charge of the ions of one sign produced in air when all the electrons and positrons liberated or created by photons in air of mass dm are completely stopped in air; thus X=dQ/dm, in units of C/kg. Exposure is also used with a second meaning to refer to the process or condition during which the x-ray tube produces x-ray radiation.

(Comment 10) One comment suggested that the definition of image intensifier be modified to add a comparison to a simple fluorescent screen.

(Response) FDA has concluded that such a change is not warranted. However, this comment prompted further review of the definition of fluoroscopy. As a result of this further review, FDA believes the proposed definition of fluoroscopy should be modified to remove the description that the images are presented instantaneously to the user. The word ''instantaneously'' is unnecessarily restrictive and ambiguous. It could result in confusion in certain situations such as when some short but finite time is required to process digital images before displaying them to the user. A further clarification has been added to note that, whereas ''fluoroscopy'' conforms to common usage in the United States, it has the same meaning as ''radioscopy'' in the IEC standards. Therefore, the definition of *fluoroscopy* is changed to read:

Fluoroscopy means a technique for generating a sequence of x-ray images and presenting them simultaneously and continuously as visible images. This term has the same meaning as the term 'radioscopy' in the standards of the International Electrotechnical Commission.

(Comment 11) One comment suggested that FDA clarify the meaning of the term ''C-arm gantry'' as used in the proposed definition of isocenter.

(Response) FDA agrees that clarification of this term would be useful and has revised the proposed definition of isocenter to read:

Isocenter means the center of the smallest sphere through which the beam axis passes when the equipment moves through a full range of rotations about its common center.

(Comment 12) Several comments suggested that FDA clarify the proposed definition of mode of operation.

(Response) FDA agrees that clarification is needed and has modified this definition. Mode of operation is defined for the purpose of assuring that adequate instructions are provided to the user on how to operate the fluoroscopic system. A mode of operation is intended to describe the state of system operation in which a set of several technique factors or other control settings are selected to perform a specific type of imaging task or procedure. Within a specific mode of operation, a variety of anatomical or examination-specific technique selections may be provided, either pre-programmed, under automatic control, or manually-selected.

(Comment 13) One comment suggested that the proposed definition of mode of operation would allow wide variations in AKR within a given mode of operation and that such variations would cause conflict with several items in § 1020.30(h). The comment suggested that FDA consider using the definition and information requirements of the IEC standard IEC 60601–2–43, ''Particular Requirements for the Safety of X-Ray Equipment for Interventional Radiology'' (Ref. 1).

(Response) FDA disagrees that the proposed definition will conflict with items of information required by § 1020.30(h). It is true that specification of a mode of operation does not in itself determine the AKR produced by the mode, as variations of technique factors or other controls within a given mode of operation can produce wide variations in the amount of radiation emitted by the system. Such variation, however, does not conflict with § 1020.30(h). Proposed § 1020.30(h)(5) would require a description of each mode of operation, and § 1020.30(h)(6) would require information about the AKR and cumulative air kerma displays. These sections do not require dose data for each mode in the information to be provided to users under § 1020.30(h). The IEC standard IEC 60601–2–43 does require providing certain dose information regarding some of the operating modes for fluoroscopic systems intended for interventional uses, but this IEC requirement would not conflict with the proposed changes to the performance standard.

FDA notes that the definition it is adopting for ''mode of operation'' differs from the definition used in paragraph 2.107 of the IEC standard IEC 60601–2–43. The IEC standard defines a mode of operation for interventional x-ray equipment as ''* * * the technical state defined by a configuration of several predetermined loading factors, technique factors or other settings for radioscopy or radiography, selectable simultaneously by the operation of a single control.'' FDA does not think it necessary to limit a mode of operation to system operation selected by operation of a single control. The definition in this final rule includes methods of system operation that have specific or unique features or intended purposes about which the user should be informed in detail. The term mode of operation in this rule addresses only the information that must be provided to the user under § 1020.30(h)(5), which requires that users receive complete instructions regarding the operation and intended function of each mode of operation.

FDA does not require information related to the reference AKR for modes of operation as does the IEC standard. FDA notes that the required display of AKR will directly inform users regarding actual entrance AKRs during use. FDA has determined that it is important that users receive complete descriptions in the user's manual of all the different modes of operation and their intended purposes or types of imaging procedures for which they are designed.

The definition of mode of operation has therefore been modified to read:

Mode of operation means, for fluoroscopic systems, a distinct method of fluoroscopy or radiography provided by the manufacturer and selected with a set of several technique factors or other control settings uniquely associated with the mode. The set of distinct technique factors and control settings for the mode may be selected by the operation of a single control. Examples of distinct modes of operation include normal fluoroscopy (analog or digital), high-level control fluoroscopy, cineradiography (analog or digital), digital subtraction angiography, electronic radiography using the fluoroscopic image receptor, and photospot recording. In a specific mode of operation, certain system variables affecting air kerma, AKR, or image quality, such as image magnification, x-ray field size, pulse rate, pulse duration, number of pulses, SID, or optical aperture, may be adjustable or may vary; their variation per se does not comprise a mode of operation different from the one that has been selected.

(Comment 14) One comment suggested that FDA change the definition of a solid-state x-ray imaging device to make it less specific and therefore more likely to accommodate changes in technology.

(Response) FDA agrees. The definition has been modified to read:

Solid-state x-ray imaging device means an assembly, typically in a rectangular panel configuration, that intercepts x-ray photons and converts the photon energy into a modulated electronic signal representative of the x-ray image. The electronic signal is then used to create an image for display and/or storage.

(Comment 15) One comment suggested that the existing definition of visible area needs clarification with respect to its use with solid-state x-ray imaging devices. The comment suggested that the definition clarify that the visible area can include both active and inactive elements of the detector when inactive elements are within the outer borders of the overall area.

(Response) FDA has determined that modification of this definition is not necessary. FDA notes that the ''area'' cited in this definition is the overall area defined by the external dimensions of the area over which photons are detected to form an image. It includes any inactive elements that might be located between active elements of the image receptor.

(Comment 16) FDA also received comments suggesting changes to some of the existing definitions that were not proposed for modification in the proposed amendments, including the definitions for beam axis, cradle, pulsed mode, source-image receptor distance (SID), portable x-ray equipment, and stationary x-ray equipment.

(Response) FDA carefully reviewed the suggestions and has determined that no changes to these definitions are warranted at this time. However, as FDA reviewed the comments received regarding proposed changes to the definitions, it became apparent to the agency that several additional definitions would be useful to further clarify some of the terms used in the performance standard. Therefore, FDA has added new definitions for the terms air kerma rate, cumulative air kerma, and fluoroscopic irradiation time. These definitions are not intended to impose any new requirements.

The new definitions read as follows:

• *Air kerma rate (AKR)* means the air kerma per unit time.

• *Cumulative air kerma* means the total air kerma accrued from the beginning of an examination or procedure and includes all contributions from fluoroscopic and radiographic irradiation.

• *Fluoroscopic irradiation time* means the cumulative duration during an examination or procedure of operator-applied continuous pressure to the device enabling x-ray tube activation in any fluoroscopic mode of operation.

2. Information to Be Provided to Users (§ 1020.30(h))

(Comment 17) Three comments suggested an expansion of the scope of information required to be provided to users by manufacturers. These comments suggested that the manufacturer be required to provide: (1) A full set of system schematics to permit the user or a third party to troubleshoot electronic problems and perform repairs; (2) system-specific hardware and software tools to permit a qualified individual to accomplish quality assurance tests without the need for service support; or (3) appropriate tools and instructions for their use, either as part of the system or as required accessories, to permit any ''physics measurements'' needed to assure system performance.

(Response) An expansion of existing information requirements was not contemplated in the proposed rule. Such requirements could have significant impact on manufacturers of diagnostic x-ray equipment and neither should be established without a full opportunity for affected parties to comment on specific proposals, nor should such requirements be established without a thorough assessment of the potential benefits and impacts of such requirements. Therefore, FDA is not incorporating the suggested requirements into the amendments at this time.

(Comment 18) One comment supported the proposed requirement that manufacturers provide additional, detailed information regarding the variety of fluoroscopic system modes of operation. This comment suggested that manufacturers be required to provide data on the entrance AKR for each mode of operation and further suggested that such a requirement could be less costly than the proposed requirement for a display of air kerma information on fluoroscopic systems. The comment suggested that users could infer approximate patient doses from such information with a degree of accuracy comparable to that of the displayed air kerma information.

(Response) FDA considered the approach described in this comment when developing the proposal and determined that providing the user with information on patient doses through data on typical entrance air kerma rates for each mode of operation was not practical and would not have the benefits associated with a real-time display of AKR and cumulative air kerma information. In FDA's opinion, either the entrance AKR is highly variable within a given mode of operation or there are so many different modes of operation, which would require separate AKR data, as to make this approach ineffective in informing physicians about the doses delivered to a patient in a procedure. For systems with a number of operating modes, it would be difficult for the user to remember all of the various entrance AKRs. The real-time display provides this information on a continuous basis for every patient, independent of the specific mode selected. For example, interventional procedures, with their associated long exposure times, may be undertaken on a variety of types of fluoroscopic systems. It does not appear feasible to distinguish the type of system that should have the real-time display from those for which such a display would not be useful.

The real-time displays are anticipated to have dose-reduction benefits even in noninterventional procedures. Providing users with immediate information related to patient doses is expected to have an impact on use of

the equipment. In addition, the uncertainty in estimating an individual patient's specific radiation dose from a reference AKR provided for a mode of operation is expected, typically, to be much greater than the uncertainty in the real-time values displayed. This increased uncertainty is due to the wide variation in AKR possible within a given mode of operation because of variations in technique factors or other control factors, patient size and attenuation, and the specific beam orientations of an individual procedure.

(Comment 19) One comment suggested that the current wording of § 1020.30(h)(1)(i) be modified to emphasize that the adequate instructions required by the section be suitably written for physician operators.

(Response) FDA does not believe that modification of the current wording is needed. The requirement for adequate instructions embodies the concept of being adequate for the intended audience. Since diagnostic x-ray systems are prescription devices, there is a presumed level of knowledge regarding the use of x-ray equipment on the part of the users.

(Comment 20) A comment questioned the preamble statement regarding unique features of equipment that require adequate instructions regarding radiological safety procedures and the precautions needed because of these features. FDA noted that any mode of operation that yields an entrance AKR greater than 88 mGy/min should be considered a unique mode, and sufficient information should be provided to enable the user to understand the patient dose implications of using that mode. The comment questioned whether an 88 mGy/min threshold should be applied to radiographic modes and further suggested that there be a requirement that any fluoroscopic mode capable of delivering more than 88 mGy/min be explicitly listed as a mode of operation and that standardized information regarding entrance AKR be provided for each such mode.

(Response) FDA disagrees with this comment. As noted in the preamble of the proposed rule, data regarding the doses from specific modes of operation are not being required in the information for users. Rather, the newly-required AKR and cumulative air kerma displays will be relied on to provide users real-time information on air kerma at the reference location which can be related to patient dose. Values of the AKR and cumulative air kerma displayed in real-time do not necessitate adjustments for particular imaging technique factors or patient size as would standardized tabulations of AKR information printed as user information for each mode.

(Comment 21) The same comment also suggested that manufacturers be required to provide standardized AKR data for fluoroscopic modes of operation as required in IEC standard IEC 60601–2–43, including information regarding the AKR for each available frame rate possible during the normal mode of operation.

(Response) FDA did not accept this suggestion, which is also addressed in the discussion in the previous paragraphs about the definition of mode of operation. FDA notes that proposed § 1020.32(k) is being revised as described in the following paragraphs to clarify the conditions under which the display of AKR is required. Proposed § 1020.30(h)(5) has been revised to require that information be provided to users for all modes of operation that produce images using the fluoroscopic image receptor regarding the impact of the mode selected on the resulting technique factors. This includes any mode that produces radiographic images from the fluoroscopic image receptor.

(Comment 22) One comment suggested several changes to the performance standard that were not included in the proposed rule. These suggestions were that in several sections of the performance standard, where specification of the maximum kilovolts peak (kVp) or a specified kVp is stated, there should be a specification of the characteristics of the kV waveform. In particular, the comment suggested that a waveform having a voltage ripple of less than or equal to 10 percent be required. One of these sections is 1020.30(h)(2)(i), which requires the specification of the peak tube potential at which the aluminum equivalent of the minimum filtration in the beam is determined. The other is the requirement in § 1020.30(m) for the kVp at which the minimum HVL values are determined. The comment addresses the requirement that manufacturers provide information regarding the peak tube potential at which the aluminum equivalent of the beam filtration provided by the tube housing assembly or permanently in the beam is determined. The comment points out the fact that the determination of the aluminum equivalent is also dependent on the voltage waveform as well as the peak tube potential.

(Response) FDA will further consider this comment and if it determines that such a modification to the standard is warranted, a proposal will be published for public comment. Without specification of the waveform, uncertainty can be introduced into the specification of the aluminum equivalence of the filtration because this determination depends on the voltage waveform and the resulting energy spectrum of the beam. FDA notes that the IEC standard IEC 60601–1–3 (Ref. 2) that establishes the minimum HVL requirements for diagnostic x-ray systems does not specify the voltage waveform as part of the test method for determining the aluminum equivalence. Rather, the requirement is specified as a function of the selected operating x-ray tube voltage over the normal range of use and is therefore dependent on the waveform of the specific x-ray generator being tested.

When the method for determining HVL was initially established, there were fewer generator designs and voltage waveforms than there are currently. It is correct that a complete specification of equivalent filtration would require a specification of the voltage waveform with which it was determined, as well as peak tube potential. However, there are no tolerances or specifications given in the standard regarding the accuracy with which the filtration equivalent is to be specified. FDA notes that one might conclude that since no requirements exist in the standard for the accuracy of the statement regarding filtration equivalent, it does not need to be so precise as to require description of or limitation on the waveform used. Note that a similar requirement exists in 1020.30(h)(4)(ii) for beam-limiting devices.

(Comment 23) One comment strongly supported the consolidation of instructions for use of the various modes of operation of fluoroscopic systems into a single section of the user's instructions. The comment further suggested that the instructions be required to include a description of all of the controls accessible to the operator at the normal working position.

(Response) FDA does not believe that such a requirement is necessary, as FDA expects that any user's instructions will include a complete description of all controls, including any controls available at the operator's working position.

(Comment 24) Three comments expressed concern regarding the requirement in proposed § 1020.30(h)(5) that manufacturers describe specific clinical procedures or uses for which a specific mode of operation is designed or intended. The concern expressed was that the clinical use of the fluoroscopic system should not be limited by any statements required of the manufacturer

regarding the purposes of any mode of operation.

(Response) FDA agrees that clinical use of the system should not be limited to the examples provided by the manufacturer. The manner of use and the decision to use a particular mode of operation are medical decisions. In addition, the requirements of the performance standard apply only to manufacturers and do not impose requirements on the users of such systems. The requirement at § 1020.30(h)(5)(ii) has been modified to reflect that a manufacturer's descriptions of particular clinical procedures exemplifying the use of specific modes of operation do not limit when or how any mode may be used in actual clinical practice.

In addition, FDA has revised § 1020.30(h)(5)(i) to further elaborate the type of information required to be provided to users with respect to the description of modes of operation. FDA believes it is important for users to understand the manner in which a given mode of operation controls the system technique factors and that this information should be included in the description of the mode of operation.

(Comment 25) An error in the proposed rule, which was detected by FDA following publication, was pointed out by one of the comments. Proposed § 1020.30(h)(6)(i) would have required a statement by the manufacturer of the maximum deviations of the values of AKR and cumulative air kerma from their displayed values.

(Response) This requirement should have been removed from the proposed rule as it was replaced by the requirement in proposed § 1020.32(k)(7) specifying the maximum deviation allowed. Proposed § 1020.30(h)(6)(i) has been removed and § 1020.32(k)(7) has been revised to be § 1020.32(k)(6). This revision of § 1020.32(k) is described in section III.D.8 of this document.

(Comment 26) One comment suggested that, in addition to requiring instructions and schedules for calibrating and maintaining any instrumentation required for measurement or evaluation of the AKR and cumulative air kerma, § 1020.30(h)(6)(ii) should also require manufacturers to provide any hardware or software tools or accessories necessary to accomplish such calibration or maintenance.

(Response) FDA is not adding such a requirement to the standard at this time, but will consider it along with the other suggestion regarding information or equipment features that should be included in the performance standard.

3. Beam Quality—Increase in Minimum Half-Value Layer (§ 1020.30(m))

(Comment 27) One comment objected to the revision of the requirements for minimum half-value of the x-ray beam in § 1020.30(m)(1) on the grounds that the new minimum requirements for all systems should not be based on what the comment considered to be state-of-the-art equipment. The comment suggested a set of reduced minimum values.

(Response) It appears that the comment misunderstood the basis for the FDA proposal and the intent of the increased HVL values. Currently, to comply with paragraph 29.201.5 of the IEC standard IEC 60601–1–3, all x-ray systems other than mammographic and some dental x-ray systems must contain total filtration material in the x-ray beam that provides a quality equivalent filtration (using IEC terminology) of not less than 2.5 millimeters of aluminum (mm Al). Thus, all currently manufactured x-ray systems should be manufactured in a manner that assures this amount of filtration in the beam if compliance with the IEC standard is claimed. The proposal to increase the HVL requirements in the FDA standard, which must be expressed as a performance standard rather than as a design standard for a given thickness of filtration, is intended to provide HVL values that correspond to those that result from the use of a filtration corresponding to the 2.5 mm Al required by the current IEC standard. Therefore, the changes proposed for HVL will simply bring FDA's requirements into agreement with the performance provided by systems complying with the IEC standards IEC 60601–1–3 and IEC 60601–2–43. Manufacturers currently complying with the IEC standard should experience no impact from this change as all of their production should already meet the requirement. Therefore, the change suggested by the comment is not necessary.

FDA notes that several values in table 1 in proposed § 1020.30(m)(1) are being revised in order to fully agree with existing and proposed IEC standards that address the minimum HVL for diagnostic x-ray systems. The values of HVL in table 1 in proposed § 1020.30(m)(1) for several tube voltages in the column heading ''II—Other X-Ray Systems''are being changed. The changes will have no significant impact on the radiation safety provided by the amendment.

(Comment 28) In conjunction with the proposed revision of the requirements for the minimum HVL of the x-ray beam, one comment suggested a 60 kVp lower limit for intraoral dental x-ray systems. The comment suggested that systems with lower kVp capabilities are not dose efficient.

(Response) FDA notes that a previous amendment to the performance standard in 1979 increased the beam quality requirements for x-ray systems manufactured after December 1, 1980. The increased beam quality required of these systems was intended to preclude systems from operating below 70 kVp, while complying with the beam quality requirements. FDA believes that the modified requirements that became effective in 1980 limited the ability of dental intraoral x-ray systems to operate at lower voltages. FDA is not aware of information indicating that there are significant numbers of newly-manufactured systems that operate with such low voltage capability. Should FDA become aware that the current requirements are not effective in limiting the beam quality of intraoral dental x-ray systems to appropriate values, future consideration will be given to proposing an appropriate amendment.

(Comment 29) Two comments suggested that § 1020.30(m)(2) contain a requirement that the system provide an indication to the user of the amount of additional filtration that is in the beam at any time during system use. The comments did not express a preference for the location for this display, indicating that it could be at the system control console or at the operator's location. A third comment supported the addition of § 1020.30(m)(2), noting the impact of the requirement in reducing patient dose and maintaining image quality.

(Response) FDA agrees that there should be a requirement for a display of the amount of additional filtration in use because it is important that the operator of the system be able to easily determine the added filtration that is currently in use during any procedure. An active display of this information will assist the operator. Manufacturers of systems that currently do not provide such a feature will be required to redesign to implement the capability to select and add filtration.

Accordingly, FDA has modified proposed § 1020.30(m)(2) to require an indication of the additional filtration in the beam. FDA has also clarified the requirement to state that the selection or insertion of the additional filtration can be either at the option of the user or automatically accomplished as part of the selected mode of operation. FDA notes that automatic selection and concurrent modification of the

technique factors to maintain image quality is the preferred method of operation. Efficient manual use of additional filtration requires that the user make appropriate technique changes to preserve optimum image quality.

FDA notes that, through an oversight, no effective date was proposed for the new requirement in § 1020.30(m)(2). This new requirement was intended to become effective, along with all of the other new requirements, 1 year after the date of publication of the amendments in the **Federal Register**. FDA has modified proposed § 1020.30(m)(2) to reflect the effective date.

4. Aluminum Equivalent of Material Between Patient and Image Receptor (§ 1020.30(n))

(Comment 30) One comment noted that the values given in table 2 in § 1020.30(n) need to be revised as a result of the revision of § 1020.30(m)(1). According to the comment, if the values of the maximum aluminum equivalence given in table 2 are not revised to reflect the increased beam quality required by § 1020.30(m)(1) for the test voltage of 100 kVp for determining compliance with § 1020.30(n), the current requirements of table 2 in § 1020.30(n) would in effect require that items between the patient and the image receptor provide less attenuation than currently required.

(Response) The comment is correct that FDA's proposal was not intended to reduce the limits on the maximum allowed aluminum equivalence of materials between the patient and the image receptor. The comment is also correct that the values in table 2 in § 1020.30(n) were based on the beam qualities associated with the current values in table 1 in § 1020.30(m)(1), reflecting a beam quality of 2.7 mm of aluminum HVL, and not the beam quality described in the proposed revision of § 1020.30(n), which is an HVL of 3.6 mm Al at 100 kVp. However, the comment's reference to the values in table 2 in § 1020.30(n) as HVL values was incorrect, although that does not invalidate the concern raised by the comment. Therefore, FDA is revising the values in table 2 in § 1020.30(n) for the maximum aluminum equivalent of materials between the patient and image receptor to reflect requirements that are met by current products that comply with the present standard. These revised limits are consistent with the maximum limits used in current IEC standard IEC 60601–1–3 (Ref. 2). This change continues the current requirement for maximum aluminum equivalence, but has no impact on current products and will not require changes in design.

5. Modification of Certified Diagnostic X-Ray Components and Systems (§ 1020.30(q))

(Comment 31) Two comments suggested that a party other than the owner be required to certify the continued compliance of any certified system that is modified in accordance with § 1020.30(q).

(Response) The current requirement was not proposed for change and no change is considered necessary by FDA. As discussed in the preamble to the proposed rule, the requirement in § 1020.30(q)(2) states that the owner of an x-ray system may modify the system, provided that the modification does not result in a failure of the system to comply with an applicable requirement of the performance standard. In accomplishing such a modification, the owner may employ a third party with the requisite skills and knowledge to accomplish the modification in a manner that does not result in noncompliance. As the responsible party, the owner should assure that any modifications are accomplished appropriately. This can be done through contractual arrangements with the party performing the modifications to assure compliance is maintained or through any other means that satisfies the owner that compliance has not been compromised by the modification. Section 1020.30(q) does not require that owners themselves perform the modification, but rather that owners be responsible for assuring the compliance of the modified system.

(Comment 32) One comment suggested that the party performing the modification be required to certify and report the modification in a manner similar to that required of an assembler of a new x-ray system. Another recommended that the party performing the modification submit a report as required by subpart B of 21 CFR part 1002 to the owner of the x-ray system.

(Response) FDA does not see a need for the reporting of such a modification. The reporting of the assembly of an x-ray system is required to provide a mechanism for the assembler of the system to complete the certification that the system has been assembled according to the manufacturer's instructions and therefore complies with the standard. The compliance of any modified system can be verified during a routine inspection by Federal or state authorities. FDA also notes that the contractual arrangement between the owner and a party engaged by the owner to perform a modification can be structured to provide the owner with the necessary assurances that the party performing the modifications is responsible to the owner for assuring the continued compliance of the system. FDA concludes that there is no need to describe these arrangements in the standard beyond the requirement that the owner be responsible for assuring the continued compliance of any modifications to its system.

Upon reviewing the comments relating to § 1020.30(q), FDA decided, on its own initiative, to add a phrase to § 1020.30(q)(2) that was not described in the proposed rule. This phrase clarifies where the recorded information regarding an owner-initiated modification is to be maintained. The phrase specifies that the information is to be maintained with the system records.

C. Comments on Proposed Changes to § 1020.31—Radiographic Equipment

1. Field Limitation and Post Exposure Adjustment of Digital Image Size

(Comment 33) One comment suggested a change in the requirement for beam limitation on radiographic x-ray systems that was not proposed. This comment recommended that automatic collimation be required for digital radiographic systems to preclude what it referred to as ''digital masking'' of images obtained with the x-ray beam limiting device (collimator) adjusted to produce an x-ray field larger than the sensitive area of the digital image receptor. This comment expressed a concern about the operation of digital radiographic systems and the manner in which the x-ray field size is adjusted. Because digital radiographic systems permit the opportunity for post-exposure image manipulation, the comment expressed concern that adjustment following image acquisition of the area imaged or ''image cropping'' might occur, obscuring the fact that the x-ray field was not adjusted appropriately and therefore not limited to the clinical area of interest.

(Response) FDA agrees that digital image cropping in lieu of appropriate x-ray field limitation could be a concern for systems that produce digital radiographic images with a digital image receptor used in place of a film/screen cassette, or for fluoroscopic systems when used to produce a radiographic image via the fluoroscopic image receptor, analogous to use of a photospot camera for analog images. For fluoroscopy and radiography using the fluoroscopic imaging assembly, proposed § 1020.32(b)(4) and (b)(5) require that the x-ray field not exceed

the visible area of the image receptor by more than specific tolerances. These requirements for the fluoroscopic imaging assembly are intended to prevent imaging with the x-ray field adjusted to a size greater than the selected visible area of the image receptor. However, it may not be clear how this requirement applies to radiographic images at the time of later storage or display.

For radiographic images, obtained directly using a digital radiographic image receptor, such as a solid-state x-ray imaging device, or from the fluoroscopic image receptor, the comment raised the question of whether some control is needed to assure that x-ray fields are not used when they are larger than necessary for the ultimate size of the either stored or displayed image.

Neither the current standard nor the proposed amendments address the issue of post-exposure image cropping of the original image at the time of image display or image storage. In the case of a radiographic system, including a purely digital system, the current standard requires that the x-ray field size not exceed the size of the image receptor, meaning that portion of the image receptor area that has been preselected during imaging such as when using a spot-film device.

The comment addresses the concern that the x-ray field might be larger than necessary to capture the area of clinical interest and that the individual obtaining the image could ''hide'' this fact by electronically cropping the digital image for storage and display. Thus, it would not be possible for someone reviewing the image later to determine that the image was obtained with an x-ray field size larger than necessary, resulting in unnecessary patient exposure. The comment suggests some type of automatic collimation to prevent this possibility, but does not describe the automatic system envisioned. If electronic cropping of digital imaging is available post exposure, it does not appear possible to have an automatic collimation system that could anticipate how such cropping might be done to the exposure.

FDA notes that the question of electronic image cropping is a question that requires further exploration and discussion with the equipment users to determine if a requirement to address this issue is needed. The agency will review this issue and determine what the current equipment design and usage practices are. If FDA determines that a limitation on the ability to crop digital images is warranted and feasible, it will be addressed in a future proposed amendment.

2. Policy Regarding Disabled Positive Beam Limitation Systems

(Comment 34) One State radiation control agency submitted a comment expressing disappointment that FDA did not propose an amendment that would have codified its policy regarding application of the standard to x-ray systems that are reassembled and that contain positive beam limitation systems that may have previously been disabled by the owner of the system.

(Response) FDA did not propose amending the standard to include this clarification because it is not a performance requirement and the standard clearly states the performance required of stationary, general-purpose systems and the obligations of assemblers to install certified components according to the manufacturer's instructions. The performance standard originally required that stationary, general-purpose x-ray systems be equipped with beam limiting devices that provided positive beam limitation (PBL). The standard was amended in 1993 (58 FR 26386) to remove the requirement that stationary, general-purpose systems be equipped with a beam limiting device providing PBL and permitting instead beam limiting device that provides continuous adjustment of the x-ray field. Questions arose regarding the performance required of beam limiting devices that were designed and certified to provide PBL when assembled into x-ray systems that were no longer required to provide PBL.

The standard requires, in § 1020.30(d), that assemblers of diagnostic x-ray systems must install certified components according to the instructions of the component manufacturer when these certified components are installed in an x-ray system. Thus, the standard requires that, when an assembler installs a beam limiting device, including one designed to provide PBL, the beam limiting device must be installed according to the manufacturer's instructions. That is, the beam limiting device must be installed such that the PBL system functions as designed and according to the manufacturer's instructions. FDA clarified this issue via communications to manufacturers, State radiation control agencies and others that emphasized the continuing requirement that any certified component be installed according to the manufacturer's instructions. Although the installation of a beam limiting device providing PBL became optional for stationary general-purpose systems, FDA noted that the requirement to install any certified component according to manufacturer's instructions remained. Thus, a PBL system, if installed, must be installed in a manner such that it functions as designed, even though there is no longer a requirement that all stationary, general-purpose x-ray systems be provided with PBL. FDA, therefore, has concluded that the suggested amendment is not appropriate for a performance standard.

D. Comments on Proposed Changes to § 1020.32—Fluoroscopic Equipment

1. Testing for Attenuation By the Primary Protective Barrier

(Comment 35) One comment on § 1020.32(a)(2) pointed out differences between FDA's testing procedures for determining compliance with the requirements for a primary protective barrier as part of the fluoroscopic imaging assembly and the testing procedure described in paragraph 29.207.2 of IEC standard IEC 60601–1–3. The comment noted that the area of the attenuation block may be insufficient for some modern fluoroscopic image receptors that accommodate x-ray field sizes greater that 20 centimeters (cm) by 20 cm.

(Response) FDA acknowledges there may be a need for a larger attenuation block in some circumstances and, as described previously in the discussion of changes to definitions in § 1020.30(b), has modified the definition to accommodate a larger size for the attenuation block.

(Comment 36) The comment also expressed concern that, because FDA and IEC compliance testing procedures are different, manufacturers will need to perform two separate tests in order to meet both standards.

(Response) FDA notes that its performance standard does not require the manufacturer to determine compliance in any particular way. Section 1020.32(a)(2) describes how FDA will measure compliance. The manufacturer is free to use any test method that provides assurance that the product complies and is free to develop a single testing procedure that would assure compliance with both standards. The comment is incorrect, therefore, in stating that the manufacturer is required to perform two different sets of measurements to satisfy both standards.

FDA also notes that the requirements for the thickness of the attenuation block and the quantitation of the amount of radiation transmitted by the protective barrier are different in the performance standard and the IEC

standard. The thickness differences most likely arise from the conversion of linear dimensions in inches (as originally used in the standard) to centimeters. FDA considers these differences minor and notes that a manufacturer may develop a single test method that assures compliance with both requirements.

(Comment 37) The comment also suggested that FDA adopt the complete wording from the IEC standard related to the attenuation of the primary beam by the primary protective barrier in lieu of the current FDA standard.

(Response) FDA does not believe that adoption of the IEC wording regarding the attenuation of the primary beam by the primary protective barrier is necessary. Although the two standards employ different approaches, including different terms, definitions, and organizational structure, there does not appear to be a significant conflict between the two standards with regard to this issue.

2. Field Limitation for Fluoroscopic Systems

(Comment 38) One comment opposed proposed § 1020.32(b)(4) and FDA's intent to promote continuously adjustable, circular field limitation in all types of fluoroscopic systems. The comment expressed doubts about the need for such a requirement, especially for systems designed for extremity imaging only, and was concerned that the requirement would add to maintenance costs. The comment suggested that a stricter requirement would be effective only if States modify their regulations to enforce identical requirements during the useful life of the equipment.

(Response) The proposal encouraged the provision of circular or nearly circular collimation for fluoroscopic systems having circular image receptors, but does not require it. The comment provided no information about why a collimator providing nearly circular collimation would be more expensive to maintain than rectangular collimation. If adopted, the proposed requirement in § 1020.32(b)(4) would apply to affected equipment, regardless of when inspected or who is performing the inspection. FDA does not understand the assertion made in the comment that, under State regulations, the under-framed fluoroscopic field would be enlarged to fill the input phosphor. Review of the State regulations of the party who submitted the comment indicates no such requirement. Rather, this State's regulations require that the x-ray field not exceed the visible area of the image receptor. There is no requirement that the field be enlarged to match the size of the image receptor. The State's regulations do not appear to prohibit an under-framed image. FDA expects that State regulations will be modified to conform to the Federal standard because, under section 542 of the act (21 U.S.C. 360ss), States may not impose different requirements on an aspect of performance of an electronic product that is addressed by the Federal standard. FDA acknowledges that the benefit of the requirement will not be as great for fluoroscopic systems intended for examination of extremities only as it will be for general-purpose fluoroscopic systems. Nevertheless, improved collimation for these systems can reduce operator exposures from scattered radiation and improve image quality. The proposal does not require circular collimation for equipment designed only for extremity use. Systems with rectangular collimation will meet the requirement of this standard. Accordingly, no change to the proposed requirement was made in response to this comment.

(Comment 39) One comment from a radiology professional organization stated that the proposed requirements for field limitation and alignment of fluoroscopic systems were acceptable. Another comment which specifically addressed § 1020.32(b)(4)(ii)(A) and (b)(4)(ii)(B) asserted that the clarity of these proposed requirements would be improved by the addition of the words ''any linear dimension of'' before the words ''the visible area.''

(Response) FDA agrees with the suggestion to add these words and has incorporated the change into the final performance standard.

3. Air Kerma Rates

(Comment 40) One comment suggested a change to the wording of proposed § 1020.32(d)(2)(iii)(B). The comment suggested adding the phrase ''archive of the'' before the words ''image(s) after termination of exposure'' to clarify that the presence of a last-image-hold feature is not sufficient to invoke the exception to the limit on maximum entrance AKR.

(Response) FDA agrees that suggested language more accurately reflects the intent of the proposed paragraph. The presence of the last-image-hold feature, without storage of the images for later viewing, is not sufficient for the exception to apply. The wording of proposed § 1020.32(d)(2)(iii)(B) has been modified accordingly.

The agency has also decided to remove the proposed requirement that the limitation on the maximum AKR apply when images are recorded in analog format with a videotape or video-disc recorder. The proposed limitation on maximum AKR cannot be justified solely on the basis of recording technology used. The display of air kerma information will directly inform the user of the AKRs delivered by different modes. Because of the different methods and mechanisms for recording fluoroscopic images and the differences in the amount of incident radiation on the image receptor required for different clinical tasks, there is no consensus on appropriate maximum AKRs during recording of fluoroscopic images. FDA has concluded that, until such a consensus is developed, it is not appropriate to establish such limits. Therefore, the list of exceptions in § 1020.32(d)(2)(iii) specifying when the limitation on maximum AKR does not apply has been modified to remove the exclusion of analog recording. Thus, the limit on maximum AKR in the amended standard does not apply to any mode of operation involving recording from the fluoroscopic image receptor for fluoroscopic systems manufactured after the effective date of the amendments.

(Comment 41) One comment supported what it described as the attempt to establish an upper limit on AKRs during both normal and high-level control modes of fluoroscopy.

(Response) This comment reflects confusion regarding the proposed amendments and the revision of § 1020.32(d) and (e). Limits already exist on AKRs during normal and high-level control fluoroscopy. The sections are being revised for clarity; the only change is to the applicability of the exception to the maximum AKR limit to systems operated in a pulsed mode as described in the following paragraphs.

(Comment 42) One comment noted that the distinction between recording fluoroscopic images via analog or digital means is not a reasonable means of differentiating between recording methods that could have different patient dose implications.

(Response) FDA agrees that this is a legitimate concern. The limitation on the exception to the maximum AKR limit originally proposed in § 1020.32(d)(2)(iii)(B) would not be an effective way to limit AKR as there are now available digital recording products that could perform the function of previous analog recording devices. The requirements of current § 1020.32(e)(2)(i) and proposed § 1020.32(d)(2)(iii)(B) were intended to prevent bypassing the limits on maximum entrance AKRs by the addition of image recording devices to fluoroscopic systems. Rather than attempting to limit entrance AKRs in

this manner, FDA has concluded that the display of AKR and cumulative air kerma will inform operators about the amount of radiation being delivered during fluoroscopic procedures and that limits during recording cannot be appropriately justified at this time. FDA has therefore revised proposed § 1020.32(d)(2)(iii)(B) to remove the last sentence that would have imposed limits during recording of fluoroscopic images with an analog format. The standard, as amended, will not place any limits on AKR during the recording of images from the fluoroscopic image receptor. Instead, the display of AKR and cumulative air kerma at the reference location, as required by § 1020.32(k), will be relied on to inform the user regarding radiation incident on the patient during fluoroscopic procedures.

(Comment 43) One comment noted that the value for the maximum limit on AKR given in proposed § 1020.32(d)(2)(iii)(C) was expressed as 180 mGy per minute, not 176 mGy per minute, which is twice the rate of 88 mGy per minute as specified for normal fluoroscopy mode.

(Response) FDA agrees with this comment and has revised the limit to be 176 mGy per minute for consistency.

(Comment 44) One comment suggested that additional information be provided to permit the AKR at the reference location for the AKR display to be determined for the maximum permitted AKRs where the latter are determined at the measurement points specified in § 1020.32(d)(3). The comment also suggested that the measurement point for mini C-arm systems be specified at the minimum source-skin distance (SSD), which is, in fact, the measurement point specified in proposed § 1020.32(d)(3)(iv).

(Response) The requirements in § 1020.32(d) address the limit on the maximum AKR permitted for fluoroscopic x-ray systems. There is no requirement that the values obtained for AKR at the compliance measurement points specified in § 1020.32(d)(3) be provided or displayed to the user. The comment appears to request that some comparison be made available to the user regarding the AKR at the compliance measurement point and the reference location for the AKR that is displayed according to proposed § 1020.32(k). Providing information to the user regarding the maximum AKR that could result at the fluoroscopic reference location could provide additional information to the user prior to the use of a system. However, as this information will be displayed in real-time to the user during the use of the system, FDA does not see the need to add an additional requirement of the type suggested.

(Comment 45) One comment suggested that additional language be added to ensure that the entrance AKR limits are met at all times by systems that permit variation in the source-image receptor distance.

(Response) FDA notes that the current standard already includes such a requirement and, like all other requirements in § 1020.32, this requirement applies to all fluoroscopic systems unless there is a specific exception stated. FDA, therefore, does not believe the suggested addition is needed.

4. Minimum Source-Skin Distance

(Comment 46) One comment noted the difference in limits on the minimum source-skin distance permitted in the FDA performance standard and the limits specified in IEC standard 60601–1–3. The requirements addressed by the comment are those for fluoroscopic systems not intended for special surgical applications. Since its inception in 1974, the performance standard has required a minimum source-skin distance of 38 cm for stationary fluoroscopes. The IEC standard has a minimum of 30 cm for fluoroscopic systems that are not intended for use during surgery. The comment suggested a limit of 30 cm for systems labeled for interventional uses. It was suggested that a minimum of 38 cm for the source-skin distance can limit the manner of clinical use of C-arm fluoroscopes. The comment also acknowledged the provisions in both the U.S. performance standard and the IEC standard for a smaller minimum source-skin distance of 20 cm for systems intended for surgical applications. The comment noted that, although interventional uses might be considered surgical applications, the limit of 20 cm for surgical systems was too short for interventional uses.

(Response) FDA did not propose a change to the minimum source-skin distance. Furthermore, no other comments suggested that the current minimum source-skin distance should be modified. FDA will consider the issue further and, if it determines that the standard should be modified, the agency will propose the amendment at a future time.

5. Display of Cumulative Irradiation Time

(Comment 47) Six comments expressed very different views on the requirement to display the cumulative irradiation time at the fluoroscopist's position, as proposed in § 1020.32(j)(2). Two comments from manufacturers and one from a State suggested that such information was not needed at the user's working position and, in fact, could be confusing to the user. In contrast, comments from two medical professional associations whose members are users of fluoroscopy systems, a medical physicist, and a State agency strongly endorsed the proposed requirements to display the cumulative irradiation time, along with the AKR and cumulative air kerma, at the user's working position.

(Response) FDA agrees with the comments from the users of fluoroscopic systems and, accordingly, the final standard retains this requirement.

(Comment 48) One comment emphasized the importance for the user of the uniformity and consistency of the display of information and two comments suggested that FDA require that the units of measurement and manner of display be specified.

(Response) In response to these comments, FDA has revised § 1020.32(h)(2) to specify the following requirements: The display must show the irradiation time in minutes and tenths of minutes and such information must be displayed continuously; updated every 6 seconds, displayed within 6 seconds of termination of exposure, and displayed until reset. In addition, as noted in the discussion of *Definitions* mentioned previously in the document, FDA has added a definition of ''fluoroscopic irradiation time'' to § 1020.30(b) to further clarify the meaning of this term.

6. Audible Signal of Irradiation Time

(Comment 49) Five comments addressed the proposed requirement that an audible signal sound every 5 minutes during fluoroscopy to alert the fluoroscopist to the passage of irradiation time. Three of these comments supported the proposed approach of a fixed, 5-minute interval between audible signals. Two of the comments specifically addressed the question of whether the interval between audible signals should be selectable by the user and recommended against such an approach, suggesting that a variable interval could lead to confusion. One comment from a manufacturer's association suggested complete elimination of the audible signal in view of the display of the AKR and cumulative air kerma to the operator and the potential for the audible signal to be distracting to the user. However, users of fluoroscopic systems supported retaining the

requirement of an audible signal as a feature of the equipment. One manufacturer commented that the proposed requirement of an audible signal would lead to a potential conflict with the IEC standard 60601–2–7, ''Particular Requirements For the Safety of High-Voltage Generators of Diagnostic X-Ray Generators,'' which contains a requirement for an audible signal that sounds continuously until reset. The manufacturer's comment also raised a question regarding the specification of the interval between reset of the signal and the time of the next audible signal.

(Response) FDA notes the potential conflict with IEC standard 60601–2–7, and further notes that this requirement for an audible warning of elapsed fluoroscopic time predates the use of fluoroscopy in interventional procedures, which often require much more than 5 minutes of irradiation time. The need to continually reset the 5-minute timer and the lack of information about the cumulative fluoroscopic time under those circumstances indicate that the current IEC requirement should also be revised. FDA will work with the appropriate IEC committee responsible for the maintenance of IEC 60601–2–7 to encourage that it be revised to be consistent with the FDA proposal.

(Comment 50) One comment suggested that the audible signal should be required to be reset manually because a signal of 1-second duration would likely be ignored.

(Response) In view of the additional requirement for a display of air kerma information during a procedure, FDA does not think that a manual reset of the audible signal is needed or that such a requirement would add significantly to the safety of these systems. The users of fluoroscopic systems will have both the display of air kerma information and the periodically recurring audible signal to remind them of the passage of fluoroscopic irradiation time. Nevertheless, the standard should not prohibit a manual reset if the user desires such a feature. Therefore, § 1020.32(j)(2) has been modified to permit, at the option of the manufacturer, the signal to be automatically terminated after 1 second or to continue sounding until manually reset. Manufacturers may provide both options for user selection if they wish.

7. Last-Image-Hold (LIH) Feature

(Comment 51) Six comments supported the proposed requirement for the LIH feature on fluoroscopic systems. One of these comments questioned whether the LIH feature was necessary for small, extremity-only fluoroscopic systems, in view of their low radiation output.

(Response) FDA believes that, even for the small, extremity-only fluoroscopic systems, the LIH feature can reduce exposure to the patient and operator. Many of the current extremity-only systems, which are digital systems, already provide the LIH feature. FDA has determined that this requirement should apply to all fluoroscopic systems.

(Comment 52) In response to the proposed requirement that images that are the result of the LIH display be clearly labeled as LIH images, two comments stated that there are other conditions during which confusion might exist regarding whether a displayed image is the result of concurrent fluoroscopic irradiation or is a display of a stored image. This could be a concern with systems with more than one image-display device. A similar concern expressed in the comments was that, when systems may display stored images, there may be no clear indication of when the fluoroscopic x-ray tube is activated. These comments suggested that the standard include additional requirements, not contained in the proposal, for a visible indication of when fluoroscopic irradiation is initiated and when irradiation is occurring. In addition, the comments suggested that the replay of stored images also be accompanied by a clear indication that the image is a replay of a stored image and not a live fluoroscopic image.

(Response) FDA agrees it is important that the fluoroscopic system provide a clear indication of when x-rays are being produced. FDA notes that § 1020.31(j) requires radiographic systems provide a visual ''beam-on'' indicator whenever x-rays are produced. Such a requirement was not included in the performance standard applicable to fluoroscopic systems in the past because the production of the fluoroscopic image was previously a direct indication of the production of x-rays. However, with the introduction of LIH features and the serial replay of stored images, the display of an image on the fluoroscopic display is not necessarily an indication of x-ray production.

FDA also agrees it is important that users be able to easily distinguish between display of a previously recorded image(s) and live-time image. It could be a safety issue if a recorded image were mistaken for a ''live'' image (or vice versa). However, FDA needs to further consider whether the requirements suggested by the comments should be added to the performance standard.

The relevant IEC standard 60601–2–7, ''Particular Requirements for the Safety of High-Voltage Generators of Diagnostic X-Ray Generators'' (Ref. 3) (see 29.2.102 Indication of Operational States, (b) Loading state) requires a yellow light on the control panel of the high voltage generator that indicates the loading state and that there be a means for connecting a remote indication of the loading state in continuous mode. This IEC standard also requires that there be a means of connecting an audible signaling device to indicate the instant of termination of loading (radiation exposure). However, these IEC requirements do not address the comment's concern that there be a requirement for a visual signal visible from anywhere in the room.

The adequacy of the approach taken in the IEC standard is open to question if, in fact, there is a need for an indication of x-ray production during fluoroscopy at the user's position. One could ask if it is sufficient for systems to provide only the means for connecting a signal device that would be visible in the procedure room or if means for actually producing such a signal should be required as part of the system. If only the means for connection is provided, State or local authorities would have to require that it be used.

The cost of adding such a display would also have to be considered, although FDA expects that the cost would be minor because the change would only require adding an indicator if the ''means for connection'' required by the IEC standard is already incorporated in the design. Manufacturers are encouraged to provide such indicators, and FDA will urge the development of an appropriate requirement in an IEC standard. In addition, FDA will consider whether such a feature should be included in any future amendments to the performance standard that FDA may develop.

8. Display of Values of Air Kerma Rate and Cumulative Air Kerma

(Comment 53) Eight comments addressed the proposed requirement for the display of AKR and cumulative air kerma at the fluoroscopist's working position. None of these comments opposed the proposed requirement. One of the comments supported the concept, but questioned whether it is necessary to impose the requirement on small, extremity-only fluoroscopes. One professional association specifically suggested that the requirement should apply to all fluoroscopic systems.

(Response) FDA notes that even small, extremity-only systems can be used for extended surgical or interventional procedures and that the radiation output of some of these systems currently is significantly larger than the output from early versions of these types of systems. For these reasons, FDA has concluded that the requirement for air kerma display is appropriate for all fluoroscopic systems.

(Comment 54) Four of the comments raised questions or made suggestions regarding the technical details and specifics of how the air kerma information should be described or displayed. One of the comments referenced the IEC standard 60601–2–43 and the manner of air kerma display required by that standard, but it incorrectly cited the requirements of that standard.

(Response) In response to these comments, FDA has modified proposed § 1020.32(k) to require display of the AKR at the fluoroscopist's working position when the x-ray tube is activated and the number of images produced is greater than six images per second. Furthermore, the value displayed is required to be updated at least once every second. The value of the cumulative air kerma will be required to be displayed either within 5 seconds of termination of an exposure, or it can be displayed continuously and updated at least once every second. The displayed values of AKR and cumulative air kerma must be clearly distinguishable from each other. The details of the specific display means are left to the manufacturer, except that the AKR must be displayed in units of mGy/min and the cumulative air kerma in mGy.

(Comment 55) A comment from a radiology society suggested that the cumulative air kerma be displayed continuously at the operator's position at all times while fluoroscopy is used.

(Response) This comment, from an organization representing users of fluoroscopic systems, indicates that these users desire a simultaneous display of both AKR and cumulative air kerma. FDA originally had envisioned a single display that would alternate between AKR and cumulative air kerma, depending on the state of the x-ray generator. However, this physician group indicates a preference for continuous update and display of the cumulative air kerma. FDA agrees that such a display is feasible and not likely to add significant costs to meeting the requirement.

There is a potential advantage to displaying the cumulative air kerma only at the termination of exposure. This would provide an incentive to stop or interrupt the exposure to learn or view the cumulative exposure and thereby perhaps minimize exposure time. However, during most fluoroscopic procedures, the exposure is continually interrupted and thus the cumulative air kerma would often be displayed.

After reviewing the comments received from the radiology society and others regarding the proposed requirement for the display of AKR and cumulative air kerma at the fluoroscopist's working position, FDA has determined that the method of display of cumulative air kerma can be left to the manufacturer. Either a continuous display of cumulative air kerma or a display following termination of exposure will provide the user with the necessary information.

(Comment 56) One comment suggested that a statement be added to explain that the information displayed would represent the air kerma measured without scatter.

(Response) FDA notes that this information was contained in the proposed requirement and is in revised § 1020.32(k)(4).

(Comment 57) One comment suggested that an alternative requirement was needed for the description of the reference location for fluoroscopic systems that have variable source-image receptor distance.

(Response) FDA notes that the reference location is specified with respect to the table or the isocenter for a C-arm system and that, under § 1020.32(k)(4)(ii), a manufacturer may describe an alternate reference location if appropriate. Therefore, FDA has concluded that the addition suggested by this comment is not needed.

(Comment 58) One comment recommended that manufacturers be permitted to adjust or change the reference location for AKR and cumulative air kerma to a point specified by the clinical user of the system.

(Response) This comment appears to suggest that some clinical users might wish to have the air kerma display indicate the air kerma at locations other than the location identified by the manufacturer in the initial design of the system. Users might desire this alternative if they consider some other point to be more representative of the dose to the patient. FDA notes that the air kerma at any other location can be obtained by the use of a multiplicative factor that is the square of the ratio of distance from the source to the reference location to the distance from the source to the new location. Such a factor can be easily calculated. Also, it is permissible for the owner of an x-ray system to modify (or cause to be modified) the x-ray system as long as the modification does not cause the system to fail to comply with the performance standard. Therefore, an owner could request that a system be modified to display the air kerma at a point different from that originally specified by the manufacturer, under § 1020.30(q), provided the user instructions for that specific system are also appropriately modified to indicate the location of the new reference location to which the air kerma display is referenced. FDA would encourage that, for any system so modified, the modification be clearly posted or labeled so that all users are aware of the modification. Such a modification would be possible only if the manufacturer's design of the air kerma display system provides a means by which the calibration of the air kerma display could be adjusted by a factor to provide the requested display. FDA does not believe that it is necessary to require that all systems have such a capability.

(Comment 59) Four comments expressed concern about the tolerance of ±25 percent for the deviation of the displayed values of AKR and cumulative air kerma from the actual values. Several of these comments asserted that the accuracy of the corresponding display requirement in IEC standard 60601–2–43 is ±50 percent. They also pointed out that accuracy required of ionization-chamber-based dose-area-product meters specified by IEC standard IEC 60580 (Ref. 4) is ±25 percent, and that other sources of error would combine with the basic uncertainties of a measuring instrument such as a dose-area-product meter to determine the air kerma at the reference location.

(Response) FDA agrees that the standard should not require accuracy greater than is technically feasible. FDA discussed this tolerance with the TEPRSSC advisory committee during a public meeting and members of the committee expressed the opinion that the display of dose information should be as accurate as possible to provide a meaningful indication of the patient dose. These members suggested that an accuracy of better than ±50 percent should be possible. After considering factors that could contribute to the uncertainty of the display of AKR and cumulative air kerma, and the importance of having as accurate an indication as technically feasible, FDA has concluded that a tolerance of ±35 percent is appropriate. Accordingly,

proposed § 1020.32(k)(7) has been revised as § 1020.32(k)(6) and specifies a maximum uncertainty of ±35 percent and a range of AKRs and cumulative air kerma over which this accuracy is to be met. Manufacturers will need to provide a schedule of maintenance sufficient to keep the air kerma display values within these tolerances.

Also, in conjunction with considering the accuracy of the dose display, FDA noted a need to better describe the conditions under which compliance would be determined. Therefore, FDA has also included in § 1020.32(k)(6) a specification that compliance with the accuracy requirement shall be determined with measurements having an irradiation time greater than three seconds. This condition is sufficient to allow for any minimum response times associated with measuring instruments.

IV. Additional Revisions of Applicability Statements and Other Corrections

In section II.B of the proposed rule (62 FR 76056 at 76059), FDA described the need to modify the applicability statements in §§ 1020.31 and 1020.32 to clearly distinguish between radiographic and fluoroscopic imaging and to identify the type of equipment to which each section applies. This clarification was needed in conjunction with modifying the performance standard to address the new types of image receptors that have been introduced for fluoroscopy and radiography. As part of this clarification, definitions of radiography and fluoroscopy were also proposed.

Although no comments were received on the proposed modifications to the applicability statements for §§ 1020.31 and 1020.32, FDA has concluded that additional modifications of the applicability statements for both sections are necessary for clarity. These changes, which are described in the following paragraphs, are not substantive changes to the wording of both sections as contained in the proposed rule.

The proposed rule contained a proposed § 1020.30(a)(1)(i)(F) that added image receptors that are electrically powered or connected to the x-ray system, to the list of components to which the performance standard applies. This addition was proposed because FDA determined that it was necessary to include new solid-state x-ray imaging devices, which are being used for both radiography and fluoroscopy, in the list of components subject to the requirements of the performance standard.

FDA inadvertently failed to discuss the addition of proposed § 1020.30(a)(1)(i)(F) in the preamble to the proposed rule. However, the application of the performance standard to the new types of image receptors was extensively discussed in sections II.B and II.C of the preamble of the proposed rule. Thus, FDA believes that its intention to apply the standard to these types of x-ray system components was made clear. No comments were received concerning this addition to § 1020.30(a); therefore, FDA has retained this proposed paragraph in the final rule.

The application of solid-state x-ray imaging devices as the image receptors for both radiographic and fluoroscopic x-ray systems requires additional clarification in the performance standard regarding the specific requirements that apply to these components and systems containing them. Previously, the requirements of § 1020.31 for radiographic systems were understood to apply to systems when x-ray film was used to obtain static radiographic images. The requirements of § 1020.32 applied to fluoroscopic x-ray systems, including when the fluoroscopic image receptor, primarily the x-ray image intensifier tube, was used to record images such as during cineradiography or when photospot images were made. With the introduction of solid-state x-ray imaging devices, we now have the situation where image receptors with the same or very similar technology may be used in both radiographic and fluoroscopic x-ray systems. The solid-state x-ray imaging device used for fluoroscopy may also produce digital radiographic images that are essentially equivalent to images produced by solid-state x-ray imaging devices used as the image receptor in digital radiographic x-ray systems. Such similarities can raise questions about when the requirements of §§ 1020.31 or 1020.32 apply to a system using a solid-state x-ray imaging device to produce digital images.

To date, this question has not received very much, if any, discussion in the radiology community. Contrary to the situation involving x-ray film and intensifying screens in an imaging cassette, the introduction of solid-state x-ray imaging devices, which are integral parts of the electronic x-ray system, raises questions as to what are appropriate performance requirements for these systems. FDA notes that there has been no consensus developed about how requirements such as x-ray system linearity, reproducibility, and x-ray field indication and alignment may need to be modified to appropriately assure the radiation safety performance of systems using a solid-state x-ray imaging device. FDA did not specifically raise these issues in the preamble to the proposed rule.

As discussed previously in section III.A of this document (comment 5), two of the organizations commenting on the proposed rule suggested that additional action may be needed to determine appropriate performance requirements for solid-state x-ray imaging devices. FDA agrees that further investigation and development of consensus on appropriate requirements for systems using solid-state x-ray imaging devices is needed and will pursue further discussions and interactions with the radiology community to better define what these requirements should be. However, in the meantime, clarification is needed regarding how the requirements of the current standard apply to systems using new types of x-ray image receptors. FDA has modified the introductory applicability statements of §§ 1020.31 and 1020.32 to clarify how these requirements apply to such systems.

In the proposed rule, the applicability statements of §§ 1020.31 and 1020.32 were revised to replace the reference to the x-ray image intensifier tube with a reference to the fluoroscopic image receptor.

In this final rule, the applicability statements have been further revised to use the new definitions of radiography and fluoroscopy and to indicate that, when images are recorded using the fluoroscopic image receptor, the requirements of § 1020.32, not § 1020.31, will apply. Thus, if an image receptor is used for fluoroscopic imaging, the requirements of § 1020.32 apply even when radiographic images are produced using the fluoroscopic image receptor. When the image receptor ''irrespective of whether it is film-based, computed radiographic, or solid-state x-ray imaging digital technology'' is used only for radiographic imaging, the requirements of § 1020.31 will apply. FDA notes that, if new combination radiographic and fluoroscopic system designs are developed that use the same image receptor for both fluoroscopic and all conventional radiographic images, the modified applicability statements would apply only the requirements of § 1020.32 to these types of systems. FDA recognizes that this particular application of requirements may not be the optimum approach or the most appropriate control for systems using new types of image receptors. However, until a consensus is developed regarding a different approach or different requirements, FDA has

concluded that this approach to applying the requirements of §§ 1020.31 and 1020.32 is appropriate. FDA will initiate efforts to develop a consensus in the radiology community regarding the appropriate requirements that should be applied to systems using solid-state x-ray imaging devices and, if warranted, propose future revisions to the performance standard established by this final rule.

FDA also notes that a typographical error regarding the statement of effective date in the introductory paragraph of § 1020.31 has been corrected to read November 29, 1984, rather than November 28, 1984. This date was originally established as November 29, 1984 in the final rule published in the **Federal Register** of August 31, 1984 (49 FR 34698) but was incorrectly printed as November 28, 1984, in the revision of the standard published on May 3, 1993 (58 FR 26386).

In addition, there was a typographical error in the text of proposed § 1020.32(k)(5)(ii), which was intended to describe the alternate location for the reference location that manufacturers might choose to designate. This text has been corrected, so that § 1020.32(k)(4)(ii) now reads as intended, ''Alternatively, the reference location shall be at a point specified by the manufacturer to represent the location of the intersection of the x-ray beam with the patient's skin.''

V. Environmental Impact

The agency has determined under 21 CFR 25.30(i) and 25.34(c) that this action is of a 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.

VI. Paperwork Reduction Act of 1995

A. Summary

This final rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3502). The title, description, and respondent description of the information collection provisions are shown in the following paragraphs with an estimate of the annual reporting burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

FDA received no comments related to the information collection requirements or the estimate of burden in response to the proposed rule. FDA, therefore, concludes that readers of the proposed rule recognized the necessity of the information to be collected, did not disagree with FDA's estimate of the burden, and had no suggestions of alternate approaches to accomplishing the goals of the proposal.

Performance Standard for Diagnostic X-Ray Systems and Their Major Components (21 CFR 1020.30 and 1020.32 Amended)

Description: FDA is amending the performance standard for diagnostic x-ray systems by establishing, among other things, requirements for several new equipment features on all new fluoroscopic x-ray systems. In the current performance standard, § 1020.30(h) requires that manufacturers provide to purchasers of x-ray equipment, and to others upon request, manuals or instruction sheets that contain technical and safety information. This required information is necessary for all purchasers (users of the equipment) to have in order to safely operate the equipment. Section 1020.30(h) currently describes the information that must be provided.

The rule established by this document will add to § 1020.30 paragraphs (h)(5) and (h)(6) describing additional information that must be included in these manuals or instructions. In addition, § 1020.32(j)(4) specifies additional descriptive information to be included in the user manuals for fluoroscopic x-ray systems required by § 1020.30(h). This additional information contains descriptions of features of the x-ray equipment required by the amendments and information determined to be appropriate and necessary for safe operation of the equipment.

Description of Respondents: Manufacturers of fluoroscopic x-ray systems that introduce fluoroscopic x-ray systems into commerce following the effective date of these amendments. FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED AVERAGE ANNUAL REPORTING BURDEN FOR THE FIRST YEAR[1]

21 CFR Section	No. of Respondents	Annual Frequency per Respondent	Total Annual Responses	Hours per Response	Total Hours
1020.30(h)(5) and (h)(6) and 1020.32(j)(4)	20	10	200	180	36,000

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED AVERAGE ANNUAL REPORTING BURDEN FOR THE SECOND AND FOLLOWING YEAR[1]

21 CFR Section	No. of Respondents	Annual Frequency per Respondent	Total Annual Responses	Hours per Response	Total Hours
1020.30(h)(5) and (h)(6) and 1020.32(j)(4)	20	5	100	180	18,000

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

B. Estimate of Burden

As described in the assessment of the cost impact of the amendment (Ref. 5), it is estimated that there are about 20 manufacturers of fluoroscopic x-ray systems who market in the United States. Each of these manufacturers is estimated to market about 10 distinct models of fluoroscopic x-ray systems. Immediately following the effective date of the amendments, for each model of fluoroscopic x-ray system that manufacturers continue to market, each manufacturer will have to supplement the user instructions to include the additional information required by the amendments.

Manufacturers already develop, produce, and provide x-ray system user manuals or instructions containing the information necessary to operate the systems, as well as the specific information required to be provided by the existing standard in § 1020.30(h). Therefore, it is assumed that no significant additional capital, operating, or maintenance costs will be incurred by the manufacturers in connection with the provision of the newly required information. The manufacturers already have procedures and methods for developing and producing the user's manuals, and the additional information required by the amendments is expected to only add a few printed pages to these already extensive manuals or documents.

The burden that will be imposed on manufacturers by the new requirements for information in the user's manuals will be the effort required to develop, draft, review, and approve the new information. The information or data to be contained within the new user instructions will already be available to the manufacturers from their design, testing, validation, or other product development documents. The burden will consist of gathering the relevant information from these documents and preparing the additional instructions from this information.

It is estimated that about 3 weeks of professional staff time (120 hours) will be required to gather the required information for a single model of an x-ray system. It is estimated that an additional 6 weeks (240 hours) of professional staff time will be required to draft, edit, design, layout, review, and approve the new portions of the user's manual or information required by the amendments. Hence, FDA estimates a total of 360 hours to prepare the new user information that will be required for each model.

For a given manufacturer, FDA anticipates that every distinct model of fluoroscopic system will not require a separate development of this additional information. Because it is thought highly likely that several models of fluoroscopic x-ray systems from a given manufacturer will share common design aspects, it is anticipated that similar means for meeting the requirement for display of exposure time, AKR, and cumulative air kerma and the requirement for the last-image-hold feature will exist on multiple models of a single manufacturer's products. Such common design aspects for multiple models will reduce the burden on manufacturers to develop new user information. Hence, the average time required to prepare new user information for all of a manufacturer's models will be correspondingly reduced. FDA expects that the average burden will be reduced from 360 hours to about 180 hours per model, under the assumption that each set of user information for a given equipment feature design will be applicable to at least two different models of a manufacturer's fluoroscopic systems. Under this assumption, the total estimated time for preparing the new user information that will be required is 36,000 hours, as shown in table 1 in the preamble of this document.

In each succeeding year the burden will be less, as the reporting requirement will apply only to the new models developed and introduced by the manufacturers in that specific year. FDA assumes that every 2 years each manufacturer will replace each of its models with a newer model requiring new user information. The multiple system applicability of this information is accounted for by also assuming that each new model only requires 180 hours of effort to develop the required information. These assumptions result in an estimated burden of 18,000 hours for each of the years following the initial year of applicability of the amendments, as shown in table 2 of this document. The information collection burden of the current performance standard at §§ 1020.30 and 1020.32 is approved and reported under an existing information collection clearance (OMB control number 0190–0025).

The information collection requirements in this final rule have been approved under OMB control number 0910–0564. This approval expires December 31, 2006. An agency 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.

VII. Analysis of Impacts

A. Introduction

FDA has examined the impacts of this final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4) . Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive order. In addition, the final rule is a significant regulatory action as defined by Executive Order 12866 and, therefore, is subject to review.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact on small entities. An analysis of available information suggests that costs to small entities are likely to be significant, as described in the following analysis. FDA believes that this regulation will likely have a significant impact on a substantial number of small entities, and it conducted an initial regulatory flexibility analysis (IRFA) to ensure that any such impacts were assessed and to alert any potentially impacted entities of the opportunity to submit comments. No comments were received regarding the impact on small entities, and the IRFA became the final regulatory flexibility analysis without further revision (see section VII.J of this document).

Section 202(a) of the UMRA requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing any rule that includes any Federal mandate that may result in an expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million (adjusted annually for inflation) in any one year. The current threshold after adjustment for inflation is $115 million, using the most current (2003) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

The agency has conducted analyses of the final rule, including a consideration of alternatives, and has determined that the final rule is consistent with the principles set forth in the Executive order and in these statutes. The costs and benefits of the rule have been assessed in two separate analyses that are described in this section of the document and that were made available for review at the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. As reviewed in the following paragraphs, these analyses have an estimated upper limit to the annual cost of $30.8 million during the first 10 years after the effective date of the amendments using a 7-percent annual discount rate and $30.1 million using a 3-percent annual discount rate. The analysis of benefits projects an average annual amortized pecuniary savings in the first 10 years after the effective date of at least $320

million, with an estimated 90 percent confidence interval spanning a range between $88.3 million and $1.160 billion using a 7-percent annual discount rate. The same analysis of benefits using a 3-percent annual discount rate resulted in annualized benefits of $715 million, with a 90-percent confidence interval of between $197.3 million and $2.593 billion. Table 2a of this document shows the annualized costs, benefits, and net benefits of the final regulation. FDA believes this analysis of impacts complies with Executive Order 12866 and OMB Circular A–4, and that the rule is a significant regulatory action as defined by the Executive order. Because of the preliminary nature of the initial cost and benefit analyses and estimates, FDA requested comments on any aspect of their methodologies, assumptions, and projections in the proposed rule. The only comments received on any aspect of these analyses were two comments that suggested, for two different reasons, that FDA had underestimated the benefits that will result from the amendments. FDA considered these comments and determined, due to the inherent uncertainty in the benefits cited, that revision of the estimated benefits analysis is not warranted.

TABLE 2A.—SUMMARY OF ANNUALIZED COSTS, BENEFITS, AND NET BENEFITS OF THE FINAL RULE

(in millions of dollars)

Discount Rate	Annualized Costs	Annualized Benefits	Range of Annualized Benefits	Net Annualized Benefits (Modal)
3% Annual discount rate	$30.1	$715.6	$197.4 to $2,592.8	$685.5
7% Annual discount rate	$30.8	$320.3	$88.4 to $1,160.5	$289.5

B. Objective of the Rule

The primary objective of the rule is to improve the public health by reducing exposure to and detriment associated with unnecessary ionizing radiation from diagnostic x-ray systems, while maintaining the diagnostic quality of the images. The rule will meet this objective by requiring features on newly manufactured x-ray systems that physicians may use to minimize unnecessary or unnecessarily large doses of radiation that could result in adverse health effects to patients and health care personnel. Such adverse effects from x-ray exposure can include acute skin injury and an increased potential for cancer or genetic damage. The secondary objectives of this rule are to bring the performance standard up to date with recent and emerging technological advances in the design of fluoroscopic and radiographic x-ray systems and to assure appropriate radiation safety for these designs. The amendments will also align the performance standard with performance requirements in current international standards that were developed after the original publication of the performance standard in 1972. In several instances, the international standards contain more stringent requirements on aspects of system performance than the current U.S. performance standard. The changes will ensure that the different safety standards are harmonized to the extent that systems meeting one standard will not be in conflict with the other. Such harmonization of standards lessens the regulatory burdens on manufacturers desiring to market systems in the global market.

The amendments will require particular x-ray equipment features reducing unnecessary radiation exposure. FDA believes the amendments are necessary because the private market may not ensure that these equipment features will be adopted without a government mandate for such features. Purchasers in health care organizations may have insufficient incentive to demand the more expensive x-ray equipment that will be required by these new amendments because benefits accrue mainly to patients and health care providers many years in the future. Patients may not demand this equipment because they lack information and knowledge about long-term radiation risk and about the highly technical nature of x-ray equipment. Hence, FDA believes these amendments are necessary to realize the net benefits described in the following analysis.

C. Risk Assessment

The risks to health that are addressed by these amendments are the adverse effects of exposure to ionizing radiation that can result from procedures utilizing diagnostic x-ray equipment. These adverse effects are well-known and have been extensively studied and documented. They are generally categorized into two types—''deterministic'' and ''stochastic.'' Deterministic effects are those that occur with certainty in days or weeks or months following irradiation whose cumulative dose exceeds a threshold characteristic of the effect. Above the threshold, the severity of the resulting injury increases as the radiation dose increases. Examples of such effects are the development of cataracts in the lens of the eye and skin ''burns.'' Skin is the tissue that often receives the highest dose from external radiation sources such as diagnostic or therapeutic x-ray exposure. Depending on the magnitude of the dose, skin injuries from radiation can range in severity from reddening of the skin and hair loss to more serious burn-like effects including localized tissue death that may require skin grafts for treatment or may result in permanent impairment. Stochastic effects are those that do not occur with certainty, but if they appear, they generally appear as leukemia or cancer one or several decades after the radiation exposure. The probability of the effect occurring is proportional to the magnitude of the radiation dose in the tissue.

The primary risk associated with radiation is the possibility of patients developing cancer years after exposure, and the magnitude of this cancer risk is generally regarded to increase with increasing radiation dose. Consistent with the conservative approach to risk assessment described by the National Council on Radiation Protection and Measurements (Ref. 6), we assume a linear relationship between cancer risk and dose. The slope of this relationship depends on age at exposure and on gender. Our benefits analysis presented in section VII.H of this document is based on linear interpolations of cancer mortality risk per whole-body equivalent dose derived from table 4-3 of the fifth report of the Committee on the Biological Effects of Ionizing Radiations (BEIR) of the National Research Council (Ref. 7). (This report is commonly known as ''BEIR V'' and henceforth will be abbreviated that way in this document.) For reasons detailed in section VII.H of this document, in the estimations of cancer mortality risk these interpolated values are reduced by

a dose-rate effectiveness factor (DREF) of 2 for solid cancers (Ref. 8). The values used in our analysis are represented in the following graph of the excess lifetime probability of death per sievert of whole-body equivalent dose (figure 1 of this document). Equivalent dose is determined from the average radiant energy absorbed per mass of tissue or organ exposed, where this average is multiplied by a dimensionless radiation weighting factor whose magnitude accounts for the detrimental biological effectiveness of the type of radiation; the value of the radiation weighting factor is unity for x rays emitted by the equipment covered in these regulations (Ref. 13). In the International System of Units, the unit of measurement of equivalent dose is joule per kilogram (J/kg) and is given the special name ''sievert'' (Sv) (Ref. 7). ''Whole-body'' means that all of the organs and tissues of the body receive the same dose.

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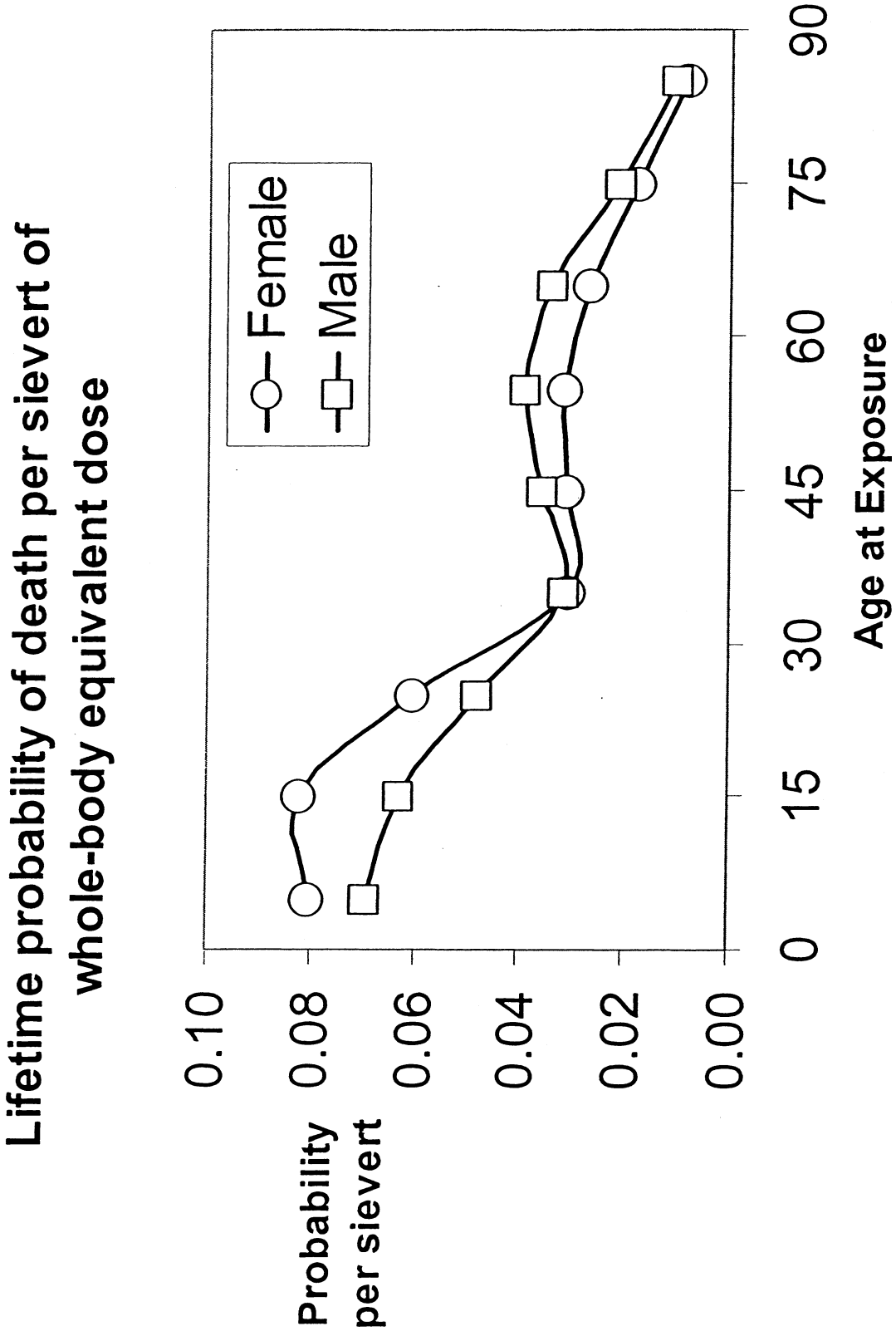
Figure 1.



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Based on Science Panel Report No. 9 (Ref. 8) of the Committee on Interagency Radiation Research and Policy (CIRRPC) of the Office of Science Technology and Policy of the Executive Office of the President, FDA underscores the overarching uncertainty in these projections with the following statement:

The estimations of radiation-associated cancer deaths were derived from linear extrapolation of nominal risk estimates for lifetime total cancer mortality from doses of 0.1 Sv. Other methods of extrapolation to the low-dose region could yield higher or lower numerical estimates of cancer deaths. At this time studies of human populations exposed at low doses are inadequate to demonstrate the actual level of risk. There is scientific uncertainty about cancer risk in the low-dose region below the range of epidemiologic observation, and the possibility of no risk cannot be excluded.

We project that the equipment features that will be required by three of the amendments will promote the bulk of radiation dose reduction and hence cancer risk reduction: (1) Displays of irradiation time, rate, and air kerma values; (2) more filtration of lower-energy x-rays; and (3) improved geometrical efficiency of the x-ray field achieved through tighter collimation. We assume that the display amendment will reduce dose on the order of 16 percent. This assumed value is one-half of a 32-percent dose reduction observed for several x-ray modalities in the United Kingdom (UK) between 1985 and 1995. We assume that one-half of the UK dose reduction was due to technology improvements alone, whereas the other half stemmed from the quality assurance use of reference dose levels and patient dose evaluation. The 16-percent dose reduction that we project for the display amendment thus presumes facility implementation of a quality assurance program making use of the displayed values. This analysis and other assumptions—6 percent dose reduction for the filtration amendment, 1 to 3 percent dose reduction for the collimation amendment—are detailed in Ref. 9. We invited comment on these assumptions in the proposed rule and received no objections to this approach. One comment suggested, based on a State's experience, that greater dose reductions would result from facilitating quality assurance programs by the requirement for air kerma display. Until recently, the principal radiation detriment for patients undergoing x-ray procedures was the risk of inducing cancer and, to a lesser extent, heritable genetic malformations. Since 1992, however, approximately 80 reports of serious radiation-induced skin injury associated with fluoroscopically-guided interventional therapeutic procedures have been published in the medical literature or reported to FDA. Many of these injuries involved significant morbidity for the affected patients. FDA's experience with reports of such adverse events leads the agency to believe that the number of these injuries is very likely underreported, given the total number of interventional procedures currently performed. Additionally, there is the lack of any clearly understood requirement or incentive for health care facilities to report such injuries. With the advance of fluoroscopic technology and the proliferating use of interventional procedures by practitioners not traditionally specializing in the field, and therefore not completely familiar with dose-sparing techniques, FDA expects an increasing risk of radiation burns that warrants the changes to the x-ray equipment performance standard obtained through the amendments.

D. Constraints on the Impact Analysis

It is FDA's opinion that the amendments will offer public health benefits that warrant their costs. However, the agency had difficulty accessing pertinent information from stakeholders to help quantify the impact of the proposal and alternatives. In view of the limited information available with which to develop estimates of the costs and benefits, FDA solicited comments, data, and opinions about whether the potential health benefits of the amendments would justify their costs. FDA received only the two limited comments cited previously on this question and, therefore, has reached a final affirmative determination as to the appropriateness of the amendments based on the earlier analyses.

The principal costs associated with the amendments will be the increased costs to produce equipment that will have the features required by the amendments. FDA has made an estimate of potential cost. The cost estimate is based on a number of assumptions designed to assure that the potential cost is not underestimated. FDA anticipates that the actual costs of these amendments may be significantly less than the upper-limit estimate developed. Manufacturers of diagnostic x-ray systems were urged to provide detailed comments on the anticipated costs of these amendments that would enable refinement of these cost estimates. No additional information was received on this topic during the comment period.

The benefits that are expected to result from these amendments are reductions in acute skin injuries and radiation-induced cancers. These benefits will result from two types of changes to the performance standard that should reduce patient dose and associated radiation detriment without compromising image quality.

The first type of change involves several new equipment features that will directly affect the intensity or size of the x-ray field. These are the requirements addressing x-ray beam quality, x-ray field limitation, limits on maximum radiation exposure rate, and the minimum source-skin distance for mini C-arm fluoroscopic systems. Almost all of the changes that directly affect x-ray field size or intensity will bring the performance standard requirements into agreement with existing international voluntary standards. To the extent that these requirements are included in voluntary standards that have a growing influence in the international marketplace, the radiological community has already recognized their benefit and appropriateness. Moreover, harmonization within a single international framework will eliminate the need for manufacturers to produce more than one line of products for a single global marketplace.

The second type of change that will be required by these amendments involves the information to be provided by the manufacturer or directly by the system itself that may be utilized by the operator to more efficiently use the x-ray system and thereby reduce patient dose. These new features are widely supported and anticipated by many knowledgeable users of fluoroscopic systems. Similar requirements were recently included in a new international voluntary standard.

There is a third type of change being made to the standard. These changes will not have a direct benefit in terms of a reduction in radiation dose. Rather, they clarify the applicability of the standard, clarify definitions, and facilitate the application of the standard to new technology and x-ray system designs.

E. Baseline Conditions

The cost of the amendments to the x-ray equipment performance standard will be borne primarily by manufacturers of fluoroscopic systems. The cost for one of the nine amendments will also affect manufacturers of radiographic equipment and is discussed in detail in Ref. 5. Therefore, this discussion will focus primarily on fluoroscopy (i.e., the

process of obtaining dynamic, real-time images of patient anatomy).

X-ray imaging is used in medicine to obtain diagnostic information on patient anatomy and disease processes or to visualize the delivery of therapeutic interventions. X-ray imaging almost always involves a tradeoff between the quality of the images needed to do the imaging task and the magnitude of the radiation exposure required to produce the image. Difficult imaging tasks may require increased radiation exposure to produce the images unless some significant technological change provides the needed image quality. Therefore, it is important that users of x-ray systems have information regarding the radiation exposures required for the images that are being produced in order to make the appropriate risk-benefit decisions.

Equipment meeting the new standards in the amendments will provide image quality and diagnostic information identical to equipment meeting current standards. Therefore, the clinical usefulness of the images provided will not change. The amendments will not affect the delivery of x-ray imaging services because the reasons for performing procedures, the number of patients having procedures, and the manner in which procedures are scheduled and conducted would not be changed as a result of the amendments. In addition, nothing in these amendments will adversely affect the clinical information or results obtained from these procedures. These amendments will result in x-ray systems having features that automatically provide for more efficient use of radiation or features that provide the physicians using the equipment with immediate information related to patient dose, thus enabling more informed and efficient use of radiation. These amendments will provide physicians using fluoroscopic equipment with the means to actively monitor the amount of radiation incident on patients and minimize unnecessary exposure or avoid doses that could result in radiation injury.

Estimates of the annual numbers of certain fluoroscopic procedures performed in the United States during the years 1996 or 1997 were developed, as described in Ref. 9, using data from several sources. These numbers of specific procedures were used in the estimates of benefit from the amendments. To keep the estimations relatively simple and conservative, no attempt was made to project the future growth in the numbers of procedures suggested by some of the literature (Ref. 9, note 27, and Ref. 25). FDA estimates that over 3 million fluoroscopically guided interventional procedures are performed each year in the United States. These procedures are described as ''interventional procedures'' because they accomplish some form of therapy for patients, often as an alternative to more invasive and risky surgical procedures. Interventional procedures may result in patient radiation doses in some patients that approach or exceed the threshold doses known to cause adverse health effects. The high doses occur because physicians utilize the fluoroscopic images throughout the entire procedure, and such procedures often require exposure times significantly longer than conventional diagnostic procedures to guide the therapy.

FDA records indicate that about 12,000 medical diagnostic x-ray systems are installed in the United States each year. Of these, about 4,200 are fluoroscopic system installations. The amendments will apply only to those new systems manufactured after the effective date, therefore affecting the 4,200 new fluoroscopic systems installed annually and a small fraction of current models of radiographic systems that do not meet the standard for x-ray beam quality.

In modeling the x-ray equipment market in the United States for the purpose of developing estimates of the cost of these amendments, FDA estimates that there are approximately a total of 40 manufacturers of diagnostic x-ray systems in the United States and half of these (20) market fluoroscopic systems and radiographic systems. It is assumed that manufacturers of radiographic systems typically market 20 models of radiographic systems, while manufacturers of fluoroscopic systems market 10 different models of fluoroscopic systems. These estimates were developed by FDA in 2000. These estimates have not been updated since publication of the proposed rule as the size of the radiographic and fluoroscopic x-ray equipment is not expected to have changed significantly in the period since 2000 and in view of the uncertainty in the original estimates.

F. The Amendments

The changes to the regulations may be considered as nine significant amendments to the current performance standard for diagnostic x-ray systems and other minor supporting changes to the standard. The nine principal amendments may be grouped into three major impact areas: (1) Amendments requiring changes to equipment design and performance that would facilitate more efficient use of radiation and provide means for reducing patient exposure, (2) amendments improving the use of fluoroscopic systems through enhanced information to users, and (3) amendments facilitating the application of the standard to new features and technologies associated with fluoroscopic systems.

Amendments requiring equipment changes include the following: Changes in x-ray beam quality; provision of a means to add additional filtration; changes in the x-ray field limitation requirements; provision of displays of values of irradiation time, AKR, and cumulative air kerma; the display of the last fluoroscopic image acquired last-image-hold feature; specification of the minimum source-skin distance for mini C-arm systems; and changes to the requirement concerning maximum limits on entrance AKR. Amendments that would result in improved information for users are those requiring additional information to be provided in user instruction manuals. Amendments facilitating the application of the standard to new technologies include the recognition of SSIX devices, revisions of the applicability sections, and establishment of additional definitions.

G. Benefits of the Amendments

The amendments will benefit patients by enabling physicians to reduce fluoroscopic radiation doses and associated detriment and, hence, to use the radiation more efficiently to achieve medical objectives. The health benefits of lowering doses are reductions in the potential for radiation induced cancers and in the numbers of skin burns associated with higher levels of x-ray exposure during fluoroscopically-guided therapeutic procedures. FDA believes that the amendments will not degrade the quality of fluoroscopic images produced while reducing the radiation doses.

There is widespread agreement in the radiological community that radiation doses to patients and staff should be kept ''as low as reasonably achievable'' (ALARA) as a general principle of radiation protection. The introduction of an increasing variety of new, fluoroscopically-guided interventional procedures, as alternatives to more invasive surgical procedures or as totally new therapies, and the use of a variety of new devices and therapies that are used with fluoroscopic guidance are resulting in significant increases in the number of fluoroscopically-guided interventional procedures with long irradiation times. Thus, the growing number of patients that are potentially at risk for acute and

long-term radiation injury makes it important to provide fluoroscopic systems with features that will assist in reducing the radiation to patients while continuing to accomplish the medical objectives of the needed procedures.

The amendments will require that fluoroscopic x-ray systems provide equipment features that directly enable the user to reduce radiation doses and maintain them ALARA. Furthermore, the amendments will require provision of information to the user of the equipment in the form of additional information in the user's manual or instructions to enable improved use in a manner that minimizes patient exposures and, by extension, occupational exposures to medical staff.

There also is widespread agreement that radiation exposures during fluoroscopy are not optimized. For example, data from the 1991 Nationwide Evaluation of X-Ray Trends (NEXT) surveys of fluoroscopic x-ray systems used for upper gastrointestinal tract examinations (upper GI exam) indicate that the mean entrance AKR is typically 5 cGy/min for an adult patient (Ref. 10). Properly maintained and adjusted fluoroscopic systems are expected to be able to perform the imaging tasks associated with the upper GI exam with an entrance AKR of 2 cGy/min or less (Ref. 11). The NEXT survey data indicate significant room for improvement in this aspect of fluoroscopic system performance. The total patient dose could be significantly reduced were the entrance AKR lowered to what is currently reasonably achievable, and the features required by the amendments will facilitate this reduction.

The new, required features of last-image-hold and real-time display of entrance AKR and cumulative entrance air kerma values are intended to provide fluoroscopists with means to better limit the patient radiation exposure. The last-image-hold feature will permit decisionmaking regarding the procedure underway while visualizing the anatomy without continuing to expose the patient. The air kerma- and AKR-value displays will provide real-time feedback to the fluoroscopists and are anticipated to result in improved fluoroscopist performance to limit radiation dose based on the immediate availability of information regarding that dose. Realization of the potential dose reduction benefits will require fluoroscopists to take advantage of these new features and optimize the way they use fluoroscopic systems.

The potential impact of the change in the beam quality requirement, which will apply to most radiographic and all fluoroscopic systems, can be seen from the data on beam quality obtained from FDA's Compliance Testing Program for the current standard. Between January 1, 1996, and December 31, 2000, FDA conducted 4,832 tests of beam quality, that is, measurement of the HVL of the beam for newly-installed x-ray systems. Of these tests, only 15 systems did not meet the current HVL or beam quality requirement. If the requirements for HVL contained in these amendments had been used as the criteria for compliance, only 698 systems or 14.4 percent of the systems tested would have been found not to have complied. This result suggests that, at a minimum, approximately 15 percent of recently installed medical x-ray systems would have their beam quality improved and patient exposures reduced were the new requirement in place and applicable to them.

Numerous examples are available in the literature that illustrate the potential reduction in patient dose, while preserving image quality, that can result from increased x-ray beam filtration. Reference 12 demonstrates that the addition of 1.5 to 2.0 mm Al as additional filtration, which is the change required to enable systems that just meet the current requirement to meet the new HVL requirement, will result in about a 30-percent reduction in entrance air kerma and about a 15 percent reduction in the integral dose for the fluoroscopic examination modeled in the paper at 80 kVp tube potential. Reduction in entrance skin dose (entrance air kerma) is relevant to reducing the risk of deterministic injuries to the skin, while a reduction in the integral dose is directly related to a reduction in the risk of stochastic effects such as cancer induction. Other authors have described dose reductions of a similar magnitude from increasing filtration for radiographic systems.

The requirements in these amendments implement many of the suggestions and recommendations developed by members of the radiological community at the 1992 Workshop on Fluoroscopy sponsored by the American College of Radiology and FDA (Ref. 11). The recommendations from this workshop stressed the need to provide users of fluoroscopy with improved features enabling more informed use of this increasingly complex equipment. In addition, three radiological professional organizations indicated their opinions to FDA that radiologists would use the new features to better manage patient radiation exposure.

H. Estimation of Benefits

Projected benefits are quantified in table 3 of this document in terms of: (1) Collective dose savings, (2) numbers of lives spared premature death associated with radiation-induced cancer, (3) collective years of life spared premature death, (4) numbers of reports of fluoroscopic skin burns precluded, and (5) pecuniary estimates associated with the preceding four items. The estimates represent average annual benefits projected to ramp up during a 10-year interval in which new fluoroscopic systems conforming to the new rules are phased into use in the United States. (FDA assumes that 10 years after the effective date of the new rules all fluoroscopic systems then in use will conform to those rules and that associated recurring benefits will continue to accrue at constant rates.) Annual pecuniary estimates that are averaged over the 10-year ramp-up interval and that are associated with prevention of cancer incidence, preclusion of premature mortality, and obviation of cancer treatment are based on the projected numbers of lives spared premature death. These pecuniary estimates are valued in current dollars using a 7-percent and, separately, using a 3-percent discount rate covering the identical 10-year evaluation period used in the cost analysis. (See section VII.I of this document.) Life benefits would be realized 20 years following exposure (after a period of 10 years of cancer latency followed by a period of 10 years of survival).

TABLE 3.—PROJECTIONS OF ANNUAL BENEFITS IN THE UNITED STATES

FOR DISPLAY, COLLIMATION, AND FILTRATION RULES APPLIED TO PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA), CARDIAC CATHETERIZATION WITH CORONARY ARTERIOGRAPHY OR ANGIOGRAPHY (CA), AND UPPER GASTROINTESTINAL FLUOROSCOPY (UGI) PROCEDURES

	5th Percentile	Mode	95th Percentile
Average Annual Dose and Life Savings in the First 10 Years After Effective Date of Rule			

TABLE 3.—PROJECTIONS OF ANNUAL BENEFITS IN THE UNITED STATES—Continued

FOR DISPLAY, COLLIMATION, AND FILTRATION RULES APPLIED TO PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA), CARDIAC CATHETERIZATION WITH CORONARY ARTERIOGRAPHY OR ANGIOGRAPHY (CA), AND UPPER GASTROINTESTINAL FLUOROSCOPY (UGI) PROCEDURES

	5th Percentile	Mode	95th Percentile
Collective dose savings (person-sievert)	3,202	7,231	16,330
Number of lives spared premature death from cancer	62	223	808
Years of life spared premature death from cancer	1,131	4,094	14,818
Number of reported skin burns precluded	0.5	1.1	2.4
Average Annual Amortized Pecuniary Savings in the First 10 Years After Effective Date of Rule	7% Discount Rate		
Prevention of premature death from cancer ($ millions)	78.61	285.03	1,032.75
Obviation of cancer treatment ($ millions)	9.71	35.21	127.56
Obviation of radiation burn treatment and loss precluded ($ millions)[1]	0.03	0.07	0.16
Total ($ millions)	88.35	320.31	1,160.00
Average Annual Amortized Pecuniary Savings in the First 10 Years After Effective Date of Rule	3% Discount Rate		
Prevention of premature death from cancer ($ millions)	178.99	649.02	2,351.60
Obviation of cancer treatment ($ millions)	18.34	66.52	241.01
Obviation of radiation burn treatment and loss precluded ($ millions)[1]	0.03	0.07	0.16
Total ($ millions)	197.36	715.61	2,592.77

[1] There is no amortization for savings associated with obviation of radiation burn treatment and loss because the interval for latency, presentation, and treatment of skin injury generally occurs within a year of radiation exposure.

Columns in table 3 of this document labeled ''Mode,'' ''5th Percentile,'' and ''95th Percentile'' categorize the results of a sensitivity analysis performed to account for uncertainties in the principal variables used to compute the data contained in the rows of table 3. The columns correspond to the expected (mode) and extremum values of 90-percent confidence intervals associated with the estimated benefits. Estimation of these uncertainties is discussed following descriptions of the row categories in table 3.

Collective dose savings (quantified in units of person-Sv) are the estimated reductions in radiation dose to the U.S. population projected to result following implementation of the amended regulations. Collective dose savings are evaluated in terms of the number of persons receiving a procedure (Ref. 9, notes 26 and 29, and Ref. 24) multiplied by the associated effective dose reduction (quantified in units of Sv) per procedure (Ref. 9, notes 28 and 42). The unit ''person-Sv'' is a product of the number of persons receiving a procedure and the number of Sv per procedure, where Sv is the unit of measurement of effective dose as well as equivalent dose, defined previously. Effective dose is the weighted sum of equivalent doses in all of the organs; it represents a level of radiation detriment equal to that for whole-body irradiation (Ref. 13), and we use it as an approximation of whole-body equivalent dose. Estimates of effective dose reduction from current levels that will result from the amendments are 16 percent for the air-kerma rate and cumulative air-kerma display requirement, 6 percent for the requirement for increased minimum x-ray filtration, and 1 to 3 percent for the requirement that would improve collimation of the x-ray field (Ref. 9, notes 9 through 13 and 18 through 25, and Refs. 12 and 15 through 23).

The number of lives spared premature death is the number of statistical deaths projected to be avoided as a result of the collective dose savings. It is essentially the product of the estimated collective dose savings described in the preceding paragraph and the radiation-associated mortality risk per Sv, represented in figure 1 of this document, summed for each gender over all ages at exposure. As illustrated in the Ref. 9 slide entitled ''Annual Life Benefit Projections in the U.S.,'' age and gender dependences are incorporated into the estimation of the number of lives spared premature death as well as into the estimation of collective dose savings and years of life spared premature death from cancer.

The years of life spared premature death from cancer is a projection evaluated as the product of the number of lives spared premature death from cancer and the difference between the actuarial number of years of life remaining and the 20-year combined interval of cancer latency and survival.

The number of skin burns precluded is projected as the percentage dose reduction multiplied by the number of skin burns reported to FDA annually, which averages approximately 8.6 reports. It is assumed that the fraction of skin doses exceeding the threshold for skin injury would be reduced in proportion to the effective-dose reduction (approximately 25 percent) projected for procedures of PTCA and CA and that therefore the number of skin burns would be reduced in the same proportion.

Estimates of average annual amortized pecuniary savings in the first 10 years after the effective date of the rule are evaluated as the respective products of two factors: (1) The projected numbers of lives spared premature death from cancer (with which obviation of cancer treatment is also associated) and (2) the monetary savings per single case associated with either prevention of premature death from cancer or obviation of cancer treatment. Pecuniary savings associated with obviation of radiation burn treatment and loss are evaluated simply as the product of the

projected number of reported skin burns precluded and the estimated pecuniary savings associated with each case of radiation burn treatment and loss precluded; although the savings associated with radiation burns are averaged over the first 10 years after the effective date of the rule, they are not amortized because the interval for latency, presentation, and treatment of skin injury generally occurs within a year of radiation exposure.

Based on an economic model of society's willingness to pay (WTP) a premium for high-risk jobs, FDA associates a value of $5 million for each statistical death avoided (Ref. 9, notes 54 through 56 and Refs. 26 through 28).

Savings of $25,000 for preclusion of each cancer treatment are estimated as follows: According to data of the U.S. National Cancer Institute (Ref. 9, note 59, and Ref. 29), 75 percent of all cancers are either stage 1 or 2 at the time of presentation. Per Ref. 9, note 60 (Ref. 30), these cancers have annual treatment costs of $23,000 to $28,000. In situ cancers are less expensive, and stage 3 and 4 cancers cost $50,000 to $60,000 annually to treat. (Also see Ref. 9, note 61, and Ref. 31.) For the FDA analysis, the annual treatment cost is estimated to be that associated with the modal stage and was estimated to be $25,000.

Savings of $5,000 for precluding each case of cancer's psychological impact are estimated as follows: Psychological impact of dread, anxiety, or depression has long been noted in cancer treatment research (e.g., see Ref. 9, notes 63 through 65, and Refs. 32 through 34). This literature indicates that symptoms associated with mental well-being contribute as much as 8 percent to one's overall sense of health. Of the sense of psychological well-being, depression scales have shown that worries about personal health account for approximately one sixth of the 8 percent contribution, where other contributors include factors associated with family, finances, work, relationships, etc. Therefore, worries and concerns about personal health contribute approximately 1.3 percent to one's sense of personal well-being. Another way to put it is that society's WTP to avoid such worries is approximately 1.3 percent of overall health costs. The WTP for overall health is derived from the estimated annual WTP of $5 million to avoid a statistical death (Ref. 9, notes 54 through 56, and Refs. 26 through 28). This value was derived from blue-collar males of about 30 years of age whose life expectancy is 41.3 years (adjusted for future expected bed and nonbed disability per Ref. 9, notes 66 and 67, and Refs. 35 and 36). Amortization of $5 million across 41.3 years at a discount rate of 7 percent implies a WTP of $373,000 per quality adjusted life-year (QALY). 1.3 percent of this QALY is approximately $5,000 per year for society's WTP to avoid the sense of psychological dread associated with concerns about personal health generated by cancer treatments.

Savings of $67,600 for each case of radiation burn treatment and loss precluded are estimated as follows: Survey data on radiation burns indicate an average medical treatment cost of $23,000 and an average work-loss cost of $20,700 (Ref. 9, note 69, and Ref. 37). Costs of pain and suffering are estimated from an index of the quality of well-being, where 1.0000 indicates perfect health, 0.0000 death (Ref. 9 notes 63, 66, and 70, and Refs. 32, 35, and 38). Relative functionality is first based on mobility (ranging from driving a car without help to being in a special care unit), social activity (ranging from working to needing help with self-care), and physical activity (ranging from walking without problems to staying in bed). Each state has been assigned a relative wellness and is adjusted according to the cause of the state (e.g., bedridden with a stomach ache versus bedridden with a broken leg). For the purpose of this analysis, FDA assigns two functional states to radiation burns: (1) Two weeks of serious debilitation (relative wellness value 0.3599) and (2) four weeks of functional distress with some activity (relative wellness value 0.5108). An annual amortized average value of $373,000 for the societal WTP for a QALY equals about $7,200 per week for a quality adjusted life week, which corresponds to the base 1.0000 in the well-being index. The estimate of the expected WTP to avoid a radiation burn is [2 x $7,200 x (1.0000 - 0.3599)] + [4 x $7,200 x (1.0000 - 0.5108)] = $23,200. Adding this value to medical treatment and work-loss costs results in a cost per burn of $67,600.

For the most part, these projections are based on a benefits analysis (Ref. 9, available at *http://www.fda.gov/cdrh/radhlth/scifor01f.pdf* or *http://www.fda.gov/cdrh/radhlth/021501_xray.html*) whose domain is intended to be representative but not exhaustive of prospective savings. To keep the analysis finite and manageable, it is limited to the three amendments (see sections II.E, II.F, and II.K of the proposed rule) that would most reduce radiation dose in several of the most common fluoroscopic procedures. The procedures considered are those of PTCA, CA, and UGI. There are other very highly-utilized fluoroscopic procedures, for example, the barium enema examination, whose dose savings might be of comparable magnitude to those of UGI, that are not included at all in this analysis. The three amendments considered would require new fluoroscopic x-ray systems to: (1) Display the rate, time, and cumulative total of radiation emission; (2) collimate the x-ray beam more efficiently; and (3) filter out more of the low energy x-ray photons from the x-ray beam. New requirements for the source-skin distance for small C-arm fluoroscopes (see section II.J of the proposed rule) and for provision of the last-image-hold feature on all fluoroscopic systems (see section II.L of the proposed rule) will also directly reduce dose, but their dose reductions are expected to be much smaller than those associated with the preceding changes. The remaining amendments can be characterized as clarifications of the applicability of the standard, changes in definitions, corrections of errors, and other changes that contribute generally to the effectiveness of implementation of the standard.

Most of the assumptions, rationales, and data sources underlying the benefit projections are explicitly detailed in Ref. 9 and its notes. That analysis, however, is incomplete insofar as it refers only to a single set of point estimates employing the BEIR V mortality risk estimates, which presume a dose-rate effectiveness factor (DREF) equal to unity; the DREF is defined as ''a factor by which the effect caused by a specific dose of radiation changes at low as compared to high dose rates'' (Ref. 7). For the sensitivity analysis whose results are tabulated in table 3 of this document, several additional assumptions are invoked. Among the most important of the underpinnings of the analysis are the projected percentage dose reductions corresponding to the three amendments considered and the dependence on the risk estimates for cancer mortality from BEIR V (Ref. 7). For the former, FDA assumes a relative uncertainty of a factor of 2 (lower or higher) to represent the range in projected dose reductions consistent with a range of confidence of about 90 percent in the findings and assumptions (Ref. 9).

With respect to the dependence on the BEIR V estimates, FDA follows two recommendations of the Office of Science and Technology Policy (OSTP) CIRRPC Science Panel Report No. 9 (Ref. 8) that represent the Federal consensus position for radiation risk benefit evaluation: First, we apply a value of 2 as the DREF in the projections of numbers of solid, non-leukemia cancers. Adopting a DREF value of 2 in

the analysis nearly halves the Ref. 9 modal point projections of the numbers of lives and years of life spared premature death from cancer. A DREF value of 2 implies that diagnostic or interventional fluoroscopy is a relatively low dose-rate modality. There are ambiguous assessments of that proposition: Although BEIR V (Ref. 7, pp. 171 and 220) considers most medical x-ray exposures to correspond to high-dose rates (for which the DREF is assumed to equal 1 for solid cancers), International Commission on Radiological Protection (ICRP) Publication 73 (Ref. 13, p. 6) states just as unequivocally that risk factors reduced by a DREF larger than 1 (i.e., for low dose-rate modalities) ''are appropriate for all diagnostic doses and to most of the doses in tissues remote from the target tissues in radiotherapy.'' Recognizing these contrary views of the detrimental biological effectiveness associated with the rates of delivery of fluoroscopic radiation, we assume a factor of 2 uncertainty in the DREF to span a 90-percent range of confidence and incorporate that uncertainty into the sensitivity analysis. The second recommendation that FDA adopts from CIRPPC Panel Report No. 9 (Ref. 8) is the interpretation that a factor of 2 relative uncertainty represents the BEIR V Committee's estimation of the 90-percent confidence interval for mortality risk estimates (Ref. 7). The latter value also agrees with that in the recent review of the United Nations Scientific Committee on the Effects of Atomic Radiation in the ''UNSCEAR 2000 Report'' (Ref. 14).

All of the contributions of relative uncertainty appropriate for the projections of collective dose savings, lives and years of life spared premature death associated with radiation-induced cancer, numbers of reports of fluoroscopic skin burns precluded, and associated pecuniary estimates are summed in quadrature. For the projected collective dose savings, the root quadrature sum yields an overall estimated relative uncertainty of a factor of 2.3 lower and higher than the modal point estimates of the projected savings. These values represent, respectively, the 5th and 95th percentile points of a 90 percent confidence interval. For the projected number of lives and years of life spared premature death, the overall estimated relative uncertainty is a factor of 3.6 lower and higher spanning a 90 percent confidence interval. Hence, these factors account for the principal sources of uncertainty in the projected dose reductions, in DREF, and in the mortality risk estimates. Applied to the sensitivity analysis, these relative factors of uncertainty comprise the bounds of variability within which the true values of table 3 quantities reside, at a 90-percent confidence level and under the modeling assumptions and discount rates indicated in preceding paragraphs of this document.

I. Costs of Implementing the Regulation

Costs to manufacturers of fluoroscopic and radiographic systems will increase due to these proposals. FDA will also experience costs for increased compliance activities. Some costs represent one-time expenditures to develop new designs or manufacturing processes to incorporate the regulatory changes. Other costs are the ongoing costs of providing improved equipment performance and features with each installed unit. FDA developed unit cost estimates for each required activity and multiplied the respective unit cost by the relevant variables in the affected industry segment. One-time costs are amortized over the estimated useful life of a fluoroscopy system (10 years) using a 7-percent discount rate. This allows costs to be analyzed as average annualized costs as well as first-year expenditures. FDA developed these cost estimates based on its experience with the industry and its knowledge regarding design and manufacturing practices of the industry. Initially, gross, upper-bound estimates were selected to ensure that expected costs were adequately addressed. The initial assumptions and estimates were posted on FDA's Web site and circulated to the affected industry for comment in July 2000. FDA received no comments on these initial, upper-bound estimates and therefore believes that they were generally in line with industry expectations. Since then, in order to refine the estimates to provide a more accurate representation of the upper-bound costs of the amendments, FDA reexamined its estimating assumptions and reduced some unit cost figures based on the expectation that future economies of scale would reduce the expense of some required features. This section presents a brief discussion of the cost estimates. A detailed description of this analysis is given in Ref. 5.

FDA has no information, indication, or economic presumption on whether costs estimated to be borne by manufacturers would be passed on to purchasers. The cost analysis therefore is limited to those parties who would be directly affected by the adoption of the amendments, namely, manufacturers and FDA itself. In the proposed rule, FDA requested information on the costs that would be imposed by these new requirements that would aid in refining the cost estimates. FDA received no comments or additional information on these costs.

1. Costs Associated With Requirements Affecting Equipment Design

The agency estimates that approximately one-half (20) of the manufacturers of x-ray systems will have to make design and manufacturing changes to comply with the revised beam quality requirements. It is estimated that a total of 200 x-ray models will be affected, with a one-time cost of at most $20,000 per model. These numbers result in an estimated first year expenditure of $4.0 million to redesign systems to meet the new beam quality requirement.

It will be necessary for manufacturers of fluoroscopic systems equipped with x-ray tubes with high heat capacity to redesign some systems to provide a means to add additional beam filtration. FDA estimates a design cost of $50,000 per model. A total of 100 models are likely to be affected for a one-time cost of $5.0 million to fluoroscopic system manufacturers. In addition, each system will cost more to manufacture because of the increased costs for components to provide the added feature. The increased cost of this added feature is estimated at $1,000 per fluoroscopic system. A total of 650 fluoroscopic systems are estimated to be installed annually with high heat capacity x-ray tubes, resulting in a total of $0.65 million in increased annual costs.

Modification of x-ray systems to meet the revised requirement for field limitation will entail either changes in installation and adjustment procedures or redesign of systems. Each fluoroscopic system will need either modification in the adjustment procedure for the collimators (for which new installation and adjustment procedures will be developed at an estimated one-time cost of $20,000 per model) or collimators will need to be redesigned at an estimated cost of $50,000 per model. FDA has assumed that half of all fluoroscopic x-ray system models (5 models each for 20 manufacturers) will need modifications to meet the new requirement, while the remainder will either meet the new requirement or could meet it through very minor modifications in the collimator adjustment procedure. For those system models not meeting the new requirement, it is assumed that a redesign of the collimator system is required at a cost of about $50,000 per model, leading to an upper-bound estimate of the total redesign cost of $5.0 million (20 manufacturers x 5

models x $50,000). All stationary fluoroscopic systems will most likely need redesigned collimators that will add an estimated additional $2,000 per new system due to increased complexity of the collimator. An annual industry cost increase of $5.0 million accounts for all 2,500 annual installations of systems with these more expensive collimators.

The modification of the requirement limiting the maximum entrance AKR and removal of the exception to the limit during recording of images will only affect the adjustment of newly-installed systems having such recording capability. This requirement is not expected to impose significant costs.

FDA is requiring that all fluoroscopic systems include displays of irradiation time, AKR, and cumulative air kerma to assist operators in keeping track of patient exposures and avoiding overexposures. Each model of fluoroscopic system will need to be redesigned (at a maximum estimated cost of $50,000 per model) for an estimated one-time cost of $10.0 million (200 models x $50,000). Accessory or add-on equipment for existing fluoroscopic systems that provide similar information are currently available for an additional cost of over $10,000 per system. However, FDA expects the average manufacturing cost of including such a feature as an integral feature of a fluoroscopic system to be less than $4,000 per system, due to achievable economies of scale and integration with other system computer capabilities. This assumption produces an annual cost increase of $16.8 million (4,200 annual installations x $4,000).

The amendments will require that all newly-manufactured fluoroscopic systems be provided with LIH capability. FDA expects that 10 fluoroscopic system manufacturers will need to redesign their systems to include this technology at a maximum cost of $100,000 per manufacturer. Total one-time design costs will equal $1.0 million for the industry (10 manufacturers x $100,000). It is estimated that about half of the new systems installed will already be equipped with this feature. Thus, about half of the newly-installed systems that currently do not provide this feature will need it. FDA estimates that the cost will be an additional $2,000 for each system required to have this feature. Thus, annual costs will increase by $4.2 million (2,100 annual systems x $2,000).

The clarification of the requirement for minimum source-skin distance for small C-arm systems is anticipated to require redesign of several of these systems. As there are only three manufacturers of these systems, and the redesign costs are estimated to be no more than $50,000 per system, the total one-time cost for this change will be $0.2 million. The average annualized cost of this change will be negligible.

In summary, total industry costs for compliance with the amendments in the area of equipment design include onetime costs of $25.2 million. This total equals an average annualized cost (7-percent discount rate over 10 years) of $3.6 million. The average annualized cost using a 3-percent discount rate over 10 years equals $3.0 million. In addition, annual recurring costs for new equipment features associated with these provisions are expected to equal $26.7 million.

2. Costs Associated With Additional Information for Users

The amendments will require that additional information be provided in the user instructions regarding fluoroscopic systems. FDA has estimated that each model of fluoroscopic system will need a revised and augmented instruction manual at a cost of less than $5,000 per model. This is equal to a maximum one-time cost of $1.0 million (200 models of fluoroscopic systems x $5,000) and implies maximum average annualized costs of $0.14 million (7-percent discount rate) or $0.12 million (3-percent discount rate). In addition, each newly-installed system will include an improved instruction manual. FDA estimates a cost of $20 per manual for printing and distribution of the required additional information. Each of the 4,200 installed fluoroscopy systems will include a revised manual for an annual cost of approximately $0.1 million.

Related to the requirements for additional information is the change of the quantity used to describe the radiation produced by the x-ray system. Because the change to use of the quantity air kerma does not require any changes or actions on the part of manufacturers or users, there is no significant cost associated with it.

3. Costs Associated With Clarifications and Adaptations to New Technologies

The new definitions and clarifications of applicability for the performance standard do not pose any significant new or additional costs on manufacturers.

4. FDA Costs Associated With Compliance Activities

FDA costs will increase due to the increased compliance activities that will result from these regulations. In addition, FDA will experience implementation costs in developing and publicizing the new requirements. FDA has estimated that approximately five full-time equivalent employees (FTEs) will be required to implement the regulations and conduct training of field inspectors. Using the current estimate of $117,000 per FTE, the one-time cost of implementation to FDA is approximately $0.6 million. Amortizing this cost over a 10-year evaluation period using 7- and 3-percent discount rates results in average annualized costs of about $0.1 million. Ongoing costs of annual compliance activities are expected to require about three FTEs, or a little more than $0.3 million per year.

5. Total Costs of the Regulation

The estimated costs of the amendments identified as having any significant cost impact are summarized in table 4 of this document. The costs are identified as nonrecurring costs that must be met initially or as annual costs associated with continued production of systems meeting the requirements or additional annual enforcement of the amendments. The total annualized cost of the regulations (averaged over 10 years using a 7-percent discount rate) equals $30.8 million, of which $30.4 million will be borne by manufacturers. The annualized estimate of $30.8 million represents amortization of first year costs of $53.8 million and expenditures from years 2 through 10 of $27 million annually. If costs are amortized using a 3-percent discount rate, annualized costs equal $30.1 million. The sections listed in the left-hand column of table 4 of this document refer to sections of the proposed rule.

TABLE 4.—SUMMARY OF COSTS OF AMENDMENTS

Section of the Proposed Rule Preamble Describing the Amendment	Nonrecurring Costs to Manufacturers ($ millions)	Nonrecurring Costs to FDA ($ millions)	Annual Costs to Manufacturers ($ millions)	Annual Costs to FDA ($ millions)
II.A	none	0.0059	none	none

TABLE 4.—SUMMARY OF COSTS OF AMENDMENTS—Continued

Section of the Proposed Rule Preamble Describing the Amendment	Nonrecurring Costs to Manufacturers ($ millions)	Nonrecurring Costs to FDA ($ millions)	Annual Costs to Manufacturers ($ millions)	Annual Costs to FDA ($ millions)
II.B	none	0.0324	none	none
II.D	1.0	none	0.084	0.0117
II.E	9.0	0.0117	0.650	none
II.F	5.0	0.0468	5.0	none
II.G, II.H, and II.I	none	none	none	none
II.J	0.150	0.0234	none	none
II.K	10.0	0.4680	16.8	0.2340
II.L	1.0	0.0234	4.2	none
Total	26.150	0.6026	26.734	0.2457

Therefore, during the first 10 years after the effective date of the amendments, using a 7-percent discount rate, the average annual cost is estimated to be $30.8 million, compared to projected average annual benefits of $320 million, within a range estimated between $88 million and $1.2 billion. A comparison of costs and benefits using a 3-percent discount rate results in annualized costs of $30.1 million and average annual benefits of about $716 million, within an expected range of $197 million to $2.6 billion.

J. Cost-Effectiveness of the Regulation

We evaluated the cost-effectiveness of the final regulation using the cost per incidence of cancer avoided due to lower exposure over the 10-year evaluation period. The annual numbers of future-avoided cancers due to reduced radiation doses are compared to the present values of the costs for the evaluation period. We used projections of the annual number of cancer cases that would be avoided due to the final regulation. The cases that would be avoided because of exposure reductions during the first year (as improved systems are installed) are assumed to present themselves after a 10-year latency period. We expect the overall exposure reduction attributable to this final regulation to increase by 10 percent each year as currently installed x-ray systems are replaced by systems meeting the new performance standards. The most likely estimate for reductions in the number of premature cancers resulting from reduced unnecessary exposures during the first compliant year is 66 fewer incidents of cancer. By the 10th year, the exposure reductions are expected to preclude 664 annual cancers according to the modal dose-response relationship. Table 5 of this document shows the annual decrease in cancer incidence expected for the modal relationship, as well as for the low and high range of estimated reductions.

TABLE 5.—EXPECTED ANNUAL REDUCTIONS IN CANCER INCIDENCES BY YEAR

(MODAL, LOW, AND HIGH ESTIMATES)

Compliance Year	Modal Estimate	Low Range Estimate	High Range Estimate
1	66	18	241
2	133	37	482
3	199	55	722
4	266	73	963
5	332	92	1,204
6	399	110	1,445
7	465	128	1,686
8	532	147	1,926

TABLE 5.—EXPECTED ANNUAL REDUCTIONS IN CANCER INCIDENCES BY YEAR—Continued

(MODAL, LOW, AND HIGH ESTIMATES)

Compliance Year	Modal Estimate	Low Range Estimate	High Range Estimate
9	598	165	2,167
10	664	183	2,408

Although the reductions in cancers would continue beyond the evaluation period, we have analyzed only through the 10th year.

While the dose reduction attributable to the final regulation during the first year is expected to avoid 66 future cancers, those cancers have an assumed latency of 10 years and would not be discovered until the 11th year. Therefore, while reduced exposures during year 1 are expected to avoid 66 cancers, those avoided cancers would not have occurred until year 11. Each year's expected number of future avoided cancers is discounted to arrive at an equivalent number of avoided cancers during the first year. The present equivalent number of annual cancers avoided are estimated using both 7- and 3-percent annual discount rates. These equivalent numbers are shown in table 6 of this document.

TABLE 6.—EXPECTED EQUIVALENT NUMBER OF CANCERS AVOIDED DISCOUNTED TO YEAR 1 DUE TO REGULATION

Annual Discount Rate	Modal Estimate	Low Estimate	High Estimate
3 Percent	2,217	612	8,034
7 Percent	1,173	324	4,252

The present value of the regulatory costs, when divided by the equivalent number of avoided cancers, will result in the expected cost per cancer avoided. Annualized costs using a 3-percent discount rate equaled $30.1 million and result in a present value of $256.8 million for the evaluation period. Using a 7-percent annual discount rate, annualized costs of $30.8 million result in a present value of $216.3 million. The cost per avoided cancer is shown in table 7 of this document.

TABLE 7.—REGULATORY COST-EFFECTIVENESS PER INCIDENCE OF CANCER AVOIDED DUE TO REGULATION

Annual Discount Rate	Modal Estimate	Low Estimate	High Estimate
3 Percent	$115,800	$419,600	$32,000
7 Percent	$184,400	$667,600	$50,900

The cost-effectiveness of the final regulation using a 7-percent discount rate has a modal value of $184,400 within an estimated range of between $50,900 and $667,600 per cancer avoided. If a 3-percent annual discount rate is used, the regulation will cost an estimated $115,800 per avoided cancer within an estimated range of $32,000 to $419,600.

K. Small Business Impacts

FDA believes that it is likely that the rule will have a significant impact on a substantial number of small entities and has conducted an IRFA. This analysis was designed to assess the impact of the rule on small entities and alert any impacted entities of the expected impact.

1. Description of Impact

The objective of the regulation is to reduce the likelihood of adverse events due to unnecessary exposure to radiation during diagnostic x-ray procedures, primarily fluoroscopic procedures. The amendments will accomplish this by requiring performance features on all fluoroscopic x-ray systems that will protect patients and healthcare personnel while maintaining image quality.

Manufacturers of diagnostic x-ray systems, including fluoroscopy equipment, are grouped within the North American Industry Classification System (NAICS) industry code 334517 (Irradiation Apparatus Manufacturers)[1]. The Small Business Administration (SBA) classifies as ''small'' any entity with 500 or fewer employees within this industry. Relatively small numbers of employees typify firms within this NAICS code group. About one-half of the establishments within this industry employ fewer than 20 workers, and companies have an average of 1.2 establishments per company. The manufacturers are relatively specialized, with about 84 percent of company sales coming from within the affected industry. In addition, 97 percent of all shipments of irradiation equipment originate by manufacturers classified within this industry.

The Manufacturing Industry Series report on Irradiation Apparatus Manufacturing for NAICS code 334517 from the 1997 Economic Census indicates 136 companies having 154 establishments for this industry in the United States. This report also indicates that only 15 of these establishments have 250 or more employees, with only 5 establishments having more than 500 employees. Therefore, this industry sector is predominately composed of firms meeting the SBA description of a ''small entity.'' Of the total value of shipments of $3,797,837,000 for this industry, 73 percent are from the 15 establishments with 250 or more employees. Thus, for the purposes of the IRFA, most of the diagnostic x-ray equipment manufacturing firms that will be affected by these amendments are small entities.

The impact of the amendments will be similar on manufacturers of diagnostic x-ray systems, whether or not they are small entities. This impact is the increased costs to design and manufacture x-ray systems that meet the new requirements. For those manufacturers that produce smaller numbers of systems per year, the impact of the cost of system redesign to meet the new requirements will result in a greater per unit cost impact than for manufacturers with a high volume of unit sales over which the development costs may be spread. This may have a disproportionate impact on the very small firms with a low volume of sales.

FDA considered whether there were approaches that could be taken to mitigate this impact on the firms producing the smaller numbers of systems. FDA, however, identified no feasible way to do this and also accomplish the needed public health protection. The radiation safety-related requirements are appropriate for any x-ray system, independent of the circumstances of the manufacturer. FDA considers it appropriate for any firm producing x-ray systems to provide the level of radiation protection that will be afforded by the revised standard. Patients receiving x-ray examinations or procedures warrant the same degree of radiation safety regardless of the circumstances of the manufacturer of the equipment.

2. Analysis of Alternatives

FDA examined and rejected several alternatives to proposing amendments to the performance standard. One alternative was to take no actions to modify the standard. This option was rejected because it would not permit clarification of the manner in which the standard should be applied to the technological changes occurring with fluoroscopic x-ray system design and function. This option was also rejected as failing to meet the public expectation that the federal performance standard assures adequate radiation-safety performance and features for radiographic and fluoroscopic x-ray systems. The changes that have occurred since the standard was developed in the early 1970s necessitate modification of the standard to reflect current technology and to recognize the increased radiation hazards posed by new fluoroscopic techniques and procedures.

The alternative of no action to amend the performance standard was also rejected because that alternative would continue the current situation in which the U.S. standard has some performance requirements that differ from those in several of the standards established by the IEC for diagnostic x-ray systems. Several IEC radiation-safety performance requirements are slightly more stringent than those of the U.S. standard, which has not, to date, reflected a number of changes in x-ray system technology recognized by the IEC standards. The proposed amendments will harmonize the U.S. performance standard with several of

[1] NAICS has replaced the Standard Industrial Classification (SIC) codes. NAICS Industry Group 334517 (Irradiation Apparatus) coincides with SIC Group 3844 (X–Ray Apparatus and Tubing).

the requirements of the IEC standards where differences currently exist. Such harmonization will reduce the necessity for manufacturers to comply with different requirements for products marketed in the United States versus internationally where the IEC standards are used. The no-action alternative would continue these discrepancies between the U.S. and IEC standards.

FDA considered various alternatives for each amendment that would require new equipment features or, potentially, system redesign. The assessment of the cost of each proposed amendment (listed in the first column of table 4 of this document) included consideration of alternatives to the specific amendment (Ref. 5). For amendments requiring equipment changes, consideration was given to the following factors: (1) The options or choices for specific limits or tolerances when such are imposed; (2) whether the amendment requirement should be limited to certain types of equipment or applied to all types of radiographic or fluoroscopic systems; (3) the need, where possible, to align the U.S. standard with the IEC standards and remove conflicts among the standards; and (4) whether the requirement could contribute to improved, safer use of the equipment. FDA concluded that the amendments are needed to obtain the radiation dose-reduction features necessary to facilitate safer use of fluoroscopy.

One alternative considered would be to implement only certain of the proposed amendments and omit others, as a way of reducing the overall costs of the amendments. FDA rejected this approach as inappropriate for two reasons. First, it would not result in the desired harmonization between the U.S. and international standards, one of the main goals of these amendments. Furthermore, implementing only a portion of the separate amendments would not result in the anticipated public health benefits that will result from providing users with the full range of additional system-performance information and dose-reduction features.

In the notice of proposed rulemaking (67 FR 76056, December 10, 2002) FDA requested comments on alternatives to these amendments that would accomplish the needed public health protection and, in particular, any alternatives that could mitigate the impact on small businesses. No responses to this request were received.

A portion of the unnecessary radiation exposure resulting from current fluoroscopic practices might be addressed through the establishment of controls on the qualifications and training of physicians permitted to use fluoroscopic systems. Contrary to the current situation, such requirements could help assure that all physicians using fluoroscopy were adequately trained regarding radiation-safety practices, proper fluoroscopic system use, and methods for maintaining patient doses as low as reasonably achievable. Under current law FDA does not have the authority to establish such requirements. To be effective, such a program would have to be established by States or medical professional societies or certification bodies. While recognizing that encouragement of such activities by FDA is worthwhile, reliance on such encouragement alone will not result in the needed performance improvement of fluoroscopic x-ray systems.

3. Ensuring Small Entity Participation in Rulemaking

FDA believes it is possible that the new regulations could have a significant impact on small entities. The impact will occur due to increased design and production costs for fluoroscopy systems. FDA solicited comment on the nature of this impact and whether there are reasonable alternatives that might accomplish the intended public health goals.

The proposed regulations were available on the Internet at *http://www.fda.gov* for review by all interested parties. FDA communicated the proposed regulatory changes to the x-ray equipment manufacturers' organization as well as to parties that had previously indicated an interest in amendments to the diagnostic x-ray equipment performance standard. The proposed amendments were also brought to the attention of relevant medical professional societies and organizations whose members are likely to use fluoroscopic x-ray systems.

L. Reporting Requirements and Duplicate Rules

FDA has concluded that the rule imposes new reporting and other compliance requirements on small businesses. In addition, FDA has identified no relevant Federal rules that may duplicate, overlap, or conflict with the rule.

M. Conclusion of the Analysis of Impacts

FDA has examined the impacts of the amendments to the performance standard. Based on this evaluation, an upper-bound estimate has been made for average annualized costs amounting to $30.8 million, of which $30.4 million will be borne by the manufacturers of this equipment. FDA believes that the reductions in acute and long-term radiation injuries to patients that will be facilitated by the amendments will appreciably outweigh the upper-bound costs estimated for compliance with the rules. Finally, FDA has concluded that it is likely that this proposal will have a significant impact on a substantial number of small entities. FDA solicited comment on all aspects of this analysis and all assumptions used. As noted previously in this document, only two comments were received that directly addressed the analyses and these suggested, qualitatively, that FDA had underestimated either the amount of dose reduction that will result or the benefit of such dose reduction. These comments, however, do not provide a basis for revising the estimates of costs and benefits.

VIII. Federalism

This final rule has been reviewed under Executive Order 13132, Federalism. This Executive order requires that agencies issuing regulations that have federalism implications follow certain fundamental federalism principles and provide a federalism impact statement that: (1) Demonstrates the agency consulted with appropriate State and local officials before developing the final rule, (2) summarizes State concerns, (3) provides the agency's position supporting the need for regulation, and (4) describes the extent to which the concerns of State and local officials have been met. Regulations have federalism implications whenever they have a substantial direct effect on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among various levels of government.

The Executive order indicates that, where National standards are required by Federal statutes, agencies shall consult with appropriate State and local officials in developing those standards. It also directs agencies to consult with State and local officials, to the extent practicable and permitted by law, before issuing any regulation with federalism implications that preempts State law.

In enacting the provisions of the RCHSA (which were later transferred from the PHS Act to the act by the SMDA), Congress recognized that separate State standards alone were insufficient to achieve the type of consistent and comprehensive protection that was needed. For this reason, Congress established a National radiation control program and

authorized FDA (by delegation of authority from the Secretary of the Department of Health and Human Services) to develop and administer Federal performance standards for radiation-emitting electronic products to more effectively protect the public health and safety (21 U.S.C. 360hh–360ss). To ensure that State standards would not be inconsistent with Federal performance standards for electronic products, Congress included explicit preemption language in the act. Section 542 of the act states the following:

Whenever any standard prescribed pursuant to section 534 with respect to an aspect of performance of an electronic product is in effect, no State or political subdivision of a State shall have any authority either to establish, or to continue in effect, any standard which is applicable to the same aspect of performance of such product and which is not identical to the Federal standard. Nothing in this subchapter shall be construed to prevent the Federal Government or the government of any State or political subdivision thereof from establishing a requirement with respect to emission of radiation from electronic products procured for its own use if such requirement imposes a more restrictive standard than that required to comply with the otherwise applicable Federal standard (21 U.S.C. 360ss).

Although States may not establish a performance standard for an aspect of performance of an electronic product that is not identical to the Federal standard, State and local governments do have authority to regulate the use of radiation-emitting electronic products, including diagnostic x-ray systems. Under this division of responsibility, the Federal performance standards assure that electronic products introduced into commerce possess the necessary radiation safety features. State and local governments, in turn, may prescribe who will be permitted to purchase or use such products. They may also establish requirements for facilities using these products in order to assure the safe function and operation of the products over their useful life. This division of authority and responsibility has ensured the safe use of diagnostic x-ray systems since the Federal performance standard was established in 1972.

FDA has reached out to the States and actively sought their input throughout the entire process of developing this rule. In December 1997, FDA issued an ANPRM and invited interested parties to express opinions regarding the need for amendments to the existing performance standard for diagnostic x-ray products. With the assistance of the Conference of Radiation Control Program Directors (CRCPD), a professional association whose membership includes the directors of State radiation control agencies, the ANPRM was brought to the attention of all of the State agencies responsible for radiation control. In response to the ANPRM, FDA received 12 comments, including comments from three States, one local radiation control agency, and comments from the CRCPD. In addition, beginning as early as April 1997, FDA provided opportunities for comment and discussion about the development of this rule at public meetings of FDA's TEPRSSC committee. In fact, the TEPRSSC's membership during this period included representatives of several State or local radiation control programs. Information regarding the proposed amendments was also posted on the agency's Internet Web site, and FDA informed the CRCPD of these postings.

The States also had several opportunities to participate in the development of this final rule during various CRCPD meetings at which FDA representatives were in attendance. These meetings include: The May 1998 and April 2001 National meetings, during which FDA made presentations; the May 2000 National meeting, which provided an opportunity for discussion about the amendments during the a special interest session at that meeting; and the May 2004 National meeting, during which FDA provided an update on the amendments. FDA also discussed the proposed amendments at two FDA regional meetings with State radiation control officials held in July and August of 2002.

Finally, the States had an additional opportunity to participate in the rulemaking process by submitting comments on the proposed rule. FDA specifically directed a mailing of the proposed rule to State health officials in order to encourage them to submit comments.

We received no comments from State or local officials regarding the federalism section of the proposed rule. The two states that commented on the proposed rule were generally supportive of the rule. The comments from these States have already been addressed previously in section III of this document. (See comments 1, 34, and 47.)

FDA believes that this final rule is consistent with the federalism principles expressed in Executive Order 13132. The rule only preempts State law to the extent required by statute and only on the limited aspects of performance of fluoroscopic and radiographic x-ray systems covered by this rule. In addition, FDA is not aware of any existing State or local requirements that will be displaced by this rule. The purpose of this final rule is to amend the Federal performance standard to account for changes in technology and use of fluoroscopic and radiographic x-ray systems. FDA believes these amendments are vital to ensuring the kind of consistent and effective radiation control protection Congress envisioned when it enacted the radiation control provisions of the act.

IX. References

The following references have been placed on public display in the Division of Dockets Management (see the fourth paragraph of section VII.A of this document) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site addresses, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

1. International Standard, International Electrotechnical Commission (IEC) 60601–2–43, ''Medical Electrical Equipment—Part 2–43: Particular Requirements for the Safety of X-Ray Equipment for Interventional Procedures,'' edition 1, 2000.

2. International Standard, International Electrotechnical Commission (IEC) 60601–1–3, ''Medical Electrical Equipment—Part 1: General Requirements for Safety. 3. Collateral Standard: General Requirements for Radiation Protection in Diagnostic X-Ray Equipment,'' 1994.

3. International Standard, International Electrotechnical Commission (IEC) 60601–2–7, ''Medical Electrical Equipment-Part 2–7: Particular Requirements for the Safety of High-Voltage Generators of Diagnostic X-Ray Generators,'' 2d edition, 1998.

4. International Standard, International Electrotechnical Commission (IEC) 60580, ''Medical Electrical Equipment-Dose Area Product Meters,'' 2d edition, 2000.

5. ''Assessment of the Impact of the Proposed Amendments to the Performance Standard for Diagnostic X-Ray Equipment Addressing Fluoroscopic X–Ray Systems,'' Food and Drug Administration, pp. 1–28. Also available at *http://www.fda.gov/cdrh/radhealth/fluoro/amendxrad.pdf*, November 15, 2000.

6. National Council on Radiation Protection and Measurements, ''Evaluation of the Linear-Nonthreshold Dose-Response Model for Ionizing Radiation,'' NCRP Report 136, Bethesda, MD, June 2001.

7. Upton, A.C. et al., ''Health Effects of Exposure to Low Levels of Ionizing Radiation: BEIR V,'' Committee on the Biological Effects of Ionizing Radiations, Board on Radiation Effects Research, Commission on Life Sciences, National Research Council, National Academy of Science, National Academy Press, Washington, DC, 1990.

8. Rosenstein, M. et al., Committee on Interagency Radiation Research and Policy

Coordination Science Panel Report No. 9, ''Use of BIER V and UNSCEAR 1988 in Radiation Risk Assessment, Lifetime Total Cancer Mortality Risk Estimates at Low Doses and Low Dose Rates for Low-LET Radiation,'' (ORAU 92/F–64), OSTP, EOP, Washington, DC, December 1992.

9. Stern, S.H. et al., ''Estimated Benefits of Proposed Amendments to the FDA Radiation-Safety Standard for Diagnostic X–Ray Equipment.'' (Poster presented at the 2001 FDA Science Forum, Washington, DC, February 15–16, 2001.) Also available at *http://www.fda.gov/cdrh/radhlth/021501_xray.html*.

10. Suleiman, O.H. et al., ''Nationwide Survey of Fluoroscopy: Radiation Dose and Image Quality,'' *Radiology*, vol. 203, pp. 471–476, 1997.

11. Proceedings of the ACR/FDA Workshop on Fluoroscopy, ''Strategies for Improvement in Performance, Radiation Safety and Control,'' Dulles Hyatt Hotel, Washington, DC, October 16 and 17, 1992, American College of Radiology, Merrifield, VA, 1993.

12. Gagne, R.M., P.W. Quinn, and R.J. Jennings, ''Comparison of Beam-Hardening and K–Edge Filters for Imaging Barium and Iodine During Fluoroscopy,'' *Medical Physics*, vol. 21, pp. 107–121, 1994.

13. Zuur, C. and F. Mettler, ''Radiological Protection and Safety in Medicine,'' *Annals of the ICRP*, ICRP Publication 73, vol. 26, No. 2, Pergamon Press, Oxford, UK, 1996.

14. ''Sources and Effects of Ionizing Radiation,'' United Nations Scientific Committee on the Effects of Atomic Radiation, UNSCEAR 2000 Report to the General Assembly, with Scientific Annexes, New York: United Nations, 2000.

15. Rogers A.T. et al., ''The Use of a Dose-Area Product Network to Facilitate the Establishment of Dose Reference Levels,'' *European Radiation Protection, Education and Training (ERPET), ERPET Course for Medical Physicists on Establishment of Reference Levels in Diagnostic Radiology, Passau, Germany, September 13–15, 1999, Proceedings, EC Directorate General Science, Research and Development Doc. RTD/0034/20*, (*BfS–ISH*, Oberscheissheim, July 2000), pp. 255–260.

16. Shrimpton, P.C. et al., *A National Survey of Doses to Patients Undergoing a Selection of Routine X–Ray Examinations in English Hospitals*, NRPB–R200, National Radiological Protection Board, Chilton, UK, September 1986.

17. Hart, D. et al., *Doses to Patients from Medical X–Ray Examinations in the UK—1995 Review*, NRPB–R289, National Radiological Protection Board, Chilton, UK, July 1996.

18. Kaczmarek, R., *Nationwide Evaluation of X-Ray Trends Summary of 1996 Fluoroscopy Survey*, (unpublished draft, November 2000).

19. Laitano, R.F. et al., *Energy Distributions and Air Kerma Rates of ISO and BIPM Reference Filtered X-Radiations*, Comitato Nazionale per la Ricerca e per lo Sviluppo dell'Energia Nucleare e delle Energie Alternative, p. 29, December 1990.

20. Suleiman, O.H., *Development of a Method to Calculate Organ Doses for the Upper Gastrointestinal Fluoroscopic Examination*, Ph.D. dissertation, Johns Hopkins University School of Hygiene and Public Health, Baltimore, MD, 1989.

21. Rosenstein, M. et al., *Handbook of Selected Tissue Doses for the Upper Gastrointestinal Fluoroscopic Examination*, HHS Publication FDA 92–8282, U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration, Center for Devices and Radiological Health, Rockville, MD, June 1992.

22. Geleijns, J. et al., ''A Comparison of Patient Dose for Examinations of the Upper Gastrointestinal Tract at 11 Conventional and Digital Units in The Netherlands,'' *The British Journal of Radiology*, vol. 71, pp. 745–753, July 1998.

23. Stern, S.H. et al., *Handbook of Selected Tissue Doses for Fluoroscopic and Cineangiographic Examination of the Coronary Arteries (in SI Units)*, HHS Publication FDA 95–8289, U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration, Center for Devices and Radiological Health, Rockville, MD, September 1995.

24. *Nationwide Inpatient Sample Release 6 for 1997*, compiled by HCUPnet, Healthcare Cost and Utilization Project, Agency for Healthcare Research and Quality, Rockville, MD, *http://www.ahrq.gov/data/hcup/*, August 2000.

25. Peterson, E.D. et al., ''Evolving Trends in Interventional Device Use and Outcomes: Results from the National Cardiovascular Network Database,'' *American Heart Journal*, vol. 139, no. 2, pp. 198–207, February 2000.

26. Viscusi, K., *Fatal Tradeoffs: Public and Private Responsibilities for Risk*, Oxford University Press, 1992.

27. Fisher, A. et al., ''The Value of Reducing Risks of Death: A Note on New Evidence,'' *The Journal of Policy Analysis and Management*, vol. 8, no. 1, pp. 88–100, 1989.

28. Mudarri, D., *Costs and Benefits of Smoking Restrictions: An Assessment of the Smoke-Free Environment Act of 1993*, Environmental Protection Agency, 1994.

29. U.S. National Cancer Institute, *Surveillance, Epidemiology, and End Results (SEER) Cancer Statistics Review (1973–1994), Annual*, pp. 123–143, 1997.

30. Legoretta, A. et al., ''Cost of Breast Cancer Treatment,'' *Archives of Internal Medicine*, vol. 156, pp. 2197–2201, 1996.

31. Brown, M. and L. Fintor, ''The Economic Burden of Cancer,'' *Cancer Prevention and Control*, edited by P. Greenwald et al., Marcel Dekker Inc., 1995.

32. Kaplan, R. et al., ''Health Status: Types of Validity and the Index of Well-Being,'' *Health Service Research*, winter issue, pp. 478–507, 1976.

33. Radloff, L., ''The CES–D Scale: A Self-Report Depression Scale for Research in the General Population,'' *The Journal of Applied Psychological Measurement*, vol. 1, no. 3, pp. 385–401, 1977.

34. Shrout, P., ''Scaling of Stressful Life Events,'' *Stressful Life Events and Their Contexts*, ed. by B.S. Dowrenwend and B.P. Dowenrend, Rutgers University Press, 1984.

35. Chen, M. et al., ''Social Indicators for Health Planning and Policy Analysis,'' *Policy Sciences*, vol. 6, pp. 71–89, 1975.

36. U.S. National Center for Health Statistics, *Expectation of Life and Expected Death by Race, Sex, and Age, Vital Statistics of the United States*, 1995.

37. U.S. Consumer Product Safety Commission, *Estimating the Cost to Society of Consumer Product Injuries*, CPSC–C–95–1164, National Public Services Research Institute, January 1998.

38. Kaplan, R. and J. Bush, ''Health-Related Quality of Life Measurement for Evaluation Research and Policy Analysis,'' *Health Psychology*, vol. 1, no. 1, pp. 61–80, 1982.

List of Subjects in 21 CFR Part 1020

Electronic products, Medical devices, Radiation protection, Reporting and recordkeeping requirements, Television, X-rays.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 1020 is amended as follows:

PART 1020—PERFORMANCE STANDARDS FOR IONIZING RADIATION EMITTING PRODUCTS

■ 1. The authority citation for 21 CFR part 1020 continues to read as follows:

Authority: 21 U.S.C. 351, 352, 360e–360j, 360gg–360ss, 371, 381.

■ 2. Revise § 1020.30 to read as follows:

§ 1020.30 Diagnostic x-ray systems and their major components.

(a) *Applicability*. (1) The provisions of this section are applicable to:

(i) The following components of diagnostic x-ray systems:

(A) Tube housing assemblies, x-ray controls, x-ray high-voltage generators, x-ray tables, cradles, film changers, vertical cassette holders mounted in a fixed location and cassette holders with front panels, and beam-limiting devices manufactured after August 1, 1974.

(B) Fluoroscopic imaging assemblies manufactured after August 1, 1974, and before April 26, 1977, or after June 10, 2006.

(C) Spot-film devices and image intensifiers manufactured after April 26, 1977.

(D) Cephalometric devices manufactured after February 25, 1978.

(E) Image receptor support devices for mammographic x-ray systems manufactured after September 5, 1978.

(F) Image receptors that are electrically powered or connected with the x-ray system manufactured on or after June 10, 2006.

(G) Fluoroscopic air kerma display devices manufactured on or after June 10, 2006.

(ii) Diagnostic x-ray systems, except computed tomography x-ray systems, incorporating one or more of such

components; however, such x-ray systems shall be required to comply only with those provisions of this section and §§ 1020.31 and 1020.32, which relate to the components certified in accordance with paragraph (c) of this section and installed into the systems.

(iii) Computed tomography (CT) x-ray systems manufactured before November 29, 1984.

(iv) CT gantries manufactured after September 3, 1985.

(2) The following provisions of this section and § 1020.33 are applicable to CT x-ray systems manufactured or remanufactured on or after November 29, 1984:

(i) Section 1020.30(a);

(ii) Section 1020.30(b) ''Technique factors'';

(iii) Section 1020.30(b) ''CT,'' ''Dose,'' ''Scan,'' ''Scan time,'' and ''Tomogram'';

(iv) Section 1020.30(h)(3)(vi) through (h)(3)(viii);

(v) Section 1020.30(n);

(vi) Section 1020.33(a) and (b);

(vii) Section 1020.33(c)(1) as it affects § 1020.33(c)(2); and

(viii) Section 1020.33(c)(2).

(3) The provisions of this section and § 1020.33 in its entirety, including those provisions in paragraph (a)(2) of this section, are applicable to CT x-ray systems manufactured or remanufactured on or after September 3, 1985. The date of manufacture of the CT system is the date of manufacture of the CT gantry.

(b) *Definitions*. As used in this section and §§ 1020.31, 1020.32, and 1020.33, the following definitions apply:

Accessible surface means the external surface of the enclosure or housing provided by the manufacturer.

Accessory component means:

(1) A component used with diagnostic x-ray systems, such as a cradle or film changer, that is not necessary for the compliance of the system with applicable provisions of this subchapter but which requires an initial determination of compatibility with the system; or

(2) A component necessary for compliance of the system with applicable provisions of this subchapter but which may be interchanged with similar compatible components without affecting the system's compliance, such as one of a set of interchangeable beam-limiting devices; or

(3) A component compatible with all x-ray systems with which it may be used and that does not require compatibility or installation instructions, such as a tabletop cassette holder.

Air kerma means kerma in air (see definition of *Kerma*).

Air kerma rate (AKR) means the air kerma per unit time.

Aluminum equivalent means the thickness of aluminum (type 1100 alloy)[1] affording the same attenuation, under specified conditions, as the material in question.

Articulated joint means a joint between two separate sections of a tabletop which joint provides the capacity for one of the sections to pivot on the line segment along which the sections join.

Assembler means any person engaged in the business of assembling, replacing, or installing one or more components into a diagnostic x-ray system or subsystem. The term includes the owner of an x-ray system or his or her employee or agent who assembles components into an x-ray system that is subsequently used to provide professional or commercial services.

Attenuation block means a block or stack of type 1100 aluminum alloy, or aluminum alloy having equivalent attenuation, with dimensions 20 centimeters (cm) or larger by 20 cm or larger by 3.8 cm, that is large enough to intercept the entire x-ray beam.

Automatic exposure control (AEC) means a device which automatically controls one or more technique factors in order to obtain at a preselected location(s) a required quantity of radiation.

Automatic exposure rate control (AERC) means a device which automatically controls one or more technique factors in order to obtain at a preselected location(s) a required quantity of radiation per unit time.

Beam axis means a line from the source through the centers of the x-ray fields.

Beam-limiting device means a device which provides a means to restrict the dimensions of the x-ray field.

C-arm fluoroscope means a fluoroscopic x-ray system in which the image receptor and the x-ray tube housing assembly are connected or coordinated to maintain a spatial relationship. Such a system allows a change in the direction of the beam axis with respect to the patient without moving the patient.

Cantilevered tabletop means a tabletop designed such that the unsupported portion can be extended at least 100 cm beyond the support.

Cassette holder means a device, other than a spot-film device, that supports and/or fixes the position of an x-ray film cassette during an x-ray exposure.

Cephalometric device means a device intended for the radiographic visualization and measurement of the dimensions of the human head.

Coefficient of variation means the ratio of the standard deviation to the mean value of a population of observations. It is estimated using the following equation:

$$C = \frac{s}{\overline{X}} = \frac{1}{\overline{X}}\left[\sum_{i=1}^{n}\frac{\left(X_i - \overline{X}\right)^2}{n-1}\right]^{1/2}$$

where:

s = Estimated standard deviation of the population.

$\overline{X}$ = Mean value of observations in sample.

X_i = ith observation sampled.

n = Number of observations sampled.

Computed tomography (CT) means the production of a tomogram by the acquisition and computer processing of x-ray transmission data.

Control panel means that part of the x-ray control upon which are mounted the switches, knobs, pushbuttons, and other hardware necessary for manually setting the technique factors.

Cooling curve means the graphical relationship between heat units stored and cooling time.

Cradle means:

(1) A removable device which supports and may restrain a patient above an x-ray table; or

[1] The nominal chemical composition of type 1100 aluminum alloy is 99.00 percent minimum aluminum, 0.12 percent copper, as given in ''Aluminum Standards and Data'' (1969). Copies may be obtained from The Aluminum Association, New York, NY.

(2) A device;

(i) Whose patient support structure is interposed between the patient and the image receptor during normal use;

(ii) Which is equipped with means for patient restraint; and

(iii) Which is capable of rotation about its long (longitudinal) axis.

CT gantry means tube housing assemblies, beam-limiting devices, detectors, and the supporting structures, frames, and covers which hold and/or enclose these components.

Cumulative air kerma means the total air kerma accrued from the beginning of an examination or procedure and includes all contributions from fluoroscopic and radiographic irradiation.

Diagnostic source assembly means the tube housing assembly with a beam-limiting device attached.

Diagnostic x-ray system means an x-ray system designed for irradiation of any part of the human body for the purpose of diagnosis or visualization.

Dose means the absorbed dose as defined by the International Commission on Radiation Units and Measurements. The absorbed dose, D, is the quotient of de by dm, where de is the mean energy imparted to matter of mass dm; thus D=de/dm, in units of J/kg, where the special name for the unit of absorbed dose is gray (Gy).

Equipment means x-ray equipment.

Exposure (X) means the quotient of dQ by dm where dQ is the absolute value of the total charge of the ions of one sign produced in air when all the electrons and positrons liberated or created by photons in air of mass dm are completely stopped in air; thus X=dQ/dm, in units of C/kg. A second meaning of exposure is the process or condition during which the x-ray tube produces x-ray radiation.

Field emission equipment means equipment which uses an x-ray tube in which electron emission from the cathode is due solely to action of an electric field.

Fluoroscopic air kerma display device means a device, subsystem, or component that provides the display of AKR and cumulative air kerma required by § 1020.32(k). It includes radiation detectors, if any, electronic and computer components, associated software, and data displays.

Fluoroscopic imaging assembly means a subsystem in which x-ray photons produce a set of fluoroscopic images or radiographic images recorded from the fluoroscopic image receptor. It includes the image receptor(s), electrical interlocks, if any, and structural material providing linkage between the image receptor and diagnostic source assembly.

Fluoroscopic irradiation time means the cumulative duration during an examination or procedure of operator-applied continuous pressure to the device, enabling x-ray tube activation in any fluoroscopic mode of operation.

Fluoroscopy means a technique for generating x-ray images and presenting them simultaneously and continuously as visible images. This term has the same meaning as the term ''radioscopy'' in the standards of the International Electrotechnical Commission.

General purpose radiographic x-ray system means any radiographic x-ray system which, by design, is not limited to radiographic examination of specific anatomical regions.

Half-value layer (HVL) means the thickness of specified material which attenuates the beam of radiation to an extent such that the AKR is reduced to one-half of its original value. In this definition the contribution of all scattered radiation, other than any which might be present initially in the beam concerned, is deemed to be excluded.

Image intensifier means a device, installed in its housing, which instantaneously converts an x-ray pattern into a corresponding light image of higher energy density.

Image receptor means any device, such as a fluorescent screen, radiographic film, x-ray image intensifier tube, solid-state detector, or gaseous detector, which transforms incident x-ray photons either into a visible image or into another form which can be made into a visible image by further transformations. In those cases where means are provided to preselect a portion of the image receptor, the term ''image receptor'' shall mean the preselected portion of the device.

Image receptor support device means, for mammography x-ray systems, that part of the system designed to support the image receptor during a mammographic examination and to provide a primary protective barrier.

Isocenter means the center of the smallest sphere through which the beam axis passes when the equipment moves through a full range of rotations about its common center.

Kerma means the quantity as defined by the International Commission on Radiation Units and Measurements. The kerma, K, is the quotient of dE_{tr} by dm, where dE_{tr} is the sum of the initial kinetic energies of all the charged particles liberated by uncharged particles in a mass dm of material; thus $K=dE_{tr}/dm$, in units of J/kg, where the special name for the unit of kerma is gray (Gy). When the material is air, the quantity is referred to as ''air kerma.''

Last-image-hold (LIH) radiograph means an image obtained either by retaining one or more fluoroscopic images, which may be temporally integrated, at the end of a fluoroscopic exposure or by initiating a separate and distinct radiographic exposure automatically and immediately in conjunction with termination of the fluoroscopic exposure.

Lateral fluoroscope means the x-ray tube and image receptor combination in a biplane system dedicated to the lateral projection. It consists of the lateral x-ray tube housing assembly and the lateral image receptor that are fixed in position relative to the table with the x-ray beam axis parallel to the plane of the table.

Leakage radiation means radiation emanating from the diagnostic source assembly except for:

(1) The useful beam; and

(2) Radiation produced when the exposure switch or timer is not activated.

Leakage technique factors means the technique factors associated with the diagnostic source assembly which are used in measuring leakage radiation. They are defined as follows:

(1) For diagnostic source assemblies intended for capacitor energy storage equipment, the maximum-rated peak tube potential and the maximum-rated number of exposures in an hour for operation at the maximum-rated peak tube potential with the quantity of charge per exposure being 10 millicoulombs (or 10 mAs) or the minimum obtainable from the unit, whichever is larger;

(2) For diagnostic source assemblies intended for field emission equipment rated for pulsed operation, the maximum-rated peak tube potential and the maximum-rated number of x-ray pulses in an hour for operation at the maximum-rated peak tube potential; and

(3) For all other diagnostic source assemblies, the maximum-rated peak tube potential and the maximum-rated continuous tube current for the maximum-rated peak tube potential.

Light field means that area of the intersection of the light beam from the beam-limiting device and one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the illuminance is one-fourth of the maximum in the intersection.

Line-voltage regulation means the difference between the no-load and the load line potentials expressed as a

percent of the load line potential; that is,

Percent line-voltage regulation = $100(V_n - V_i)/V_i$

where:

V_n = No-load line potential and

V_i = Load line potential.

Maximum line current means the root mean square current in the supply line of an x-ray machine operating at its maximum rating.

Mode of operation means, for fluoroscopic systems, a distinct method of fluoroscopy or radiography provided by the manufacturer and selected with a set of several technique factors or other control settings uniquely associated with the mode. The set of distinct technique factors and control settings for the mode may be selected by the operation of a single control. Examples of distinct modes of operation include normal fluoroscopy (analog or digital), high-level control fluoroscopy, cineradiography (analog or digital), digital subtraction angiography, electronic radiography using the fluoroscopic image receptor, and photospot recording. In a specific mode of operation, certain system variables affecting air kerma, AKR, or image quality, such as image magnification, x-ray field size, pulse rate, pulse duration, number of pulses, source-image receptor distance (SID), or optical aperture, may be adjustable or may vary; their variation per se does not comprise a mode of operation different from the one that has been selected.

Movable tabletop means a tabletop which, when assembled for use, is capable of movement with respect to its supporting structure within the plane of the tabletop.

Non-image-intensified fluoroscopy means fluoroscopy using only a fluorescent screen.

Peak tube potential means the maximum value of the potential difference across the x-ray tube during an exposure.

Primary protective barrier means the material, excluding filters, placed in the useful beam to reduce the radiation exposure for protection purposes.

Pulsed mode means operation of the x-ray system such that the x-ray tube current is pulsed by the x-ray control to produce one or more exposure intervals of duration less than one-half second.

Quick change x-ray tube means an x-ray tube designed for use in its associated tube housing such that:

(1) The tube cannot be inserted in its housing in a manner that would result in noncompliance of the system with the requirements of paragraphs (k) and (m) of this section;

(2) The focal spot position will not cause noncompliance with the provisions of this section or § 1020.31 or 1020.32;

(3) The shielding within the tube housing cannot be displaced; and

(4) Any removal and subsequent replacement of a beam-limiting device during reloading of the tube in the tube housing will not result in noncompliance of the x-ray system with the applicable field limitation and alignment requirements of §§ 1020.31 and 1020.32.

Radiation therapy simulation system means a radiographic or fluoroscopic x-ray system intended for localizing the volume to be exposed during radiation therapy and confirming the position and size of the therapeutic irradiation field.

Radiography means a technique for generating and recording an x-ray pattern for the purpose of providing the user with an image(s) after termination of the exposure.

Rated line voltage means the range of potentials, in volts, of the supply line specified by the manufacturer at which the x-ray machine is designed to operate.

Rated output current means the maximum allowable load current of the x-ray high-voltage generator.

Rated output voltage means the allowable peak potential, in volts, at the output terminals of the x-ray high-voltage generator.

Rating means the operating limits specified by the manufacturer.

Recording means producing a retrievable form of an image resulting from x-ray photons.

Scan means the complete process of collecting x-ray transmission data for the production of a tomogram. Data may be collected simultaneously during a single scan for the production of one or more tomograms.

Scan time means the period of time between the beginning and end of x-ray transmission data accumulation for a single scan.

Solid state x-ray imaging device means an assembly, typically in a rectangular panel configuration, that intercepts x-ray photons and converts the photon energy into a modulated electronic signal representative of the x-ray intensity over the area of the imaging device. The electronic signal is then used to create an image for display and/or storage.

Source means the focal spot of the x-ray tube.

Source-image receptor distance (SID) means the distance from the source to the center of the input surface of the image receptor.

Source-skin distance (SSD) means the distance from the source to the center of the entrant x-ray field in the plane tangent to the patient skin surface.

Spot-film device means a device intended to transport and/or position a radiographic image receptor between the x-ray source and fluoroscopic image receptor. It includes a device intended to hold a cassette over the input end of the fluoroscopic image receptor for the purpose of producing a radiograph.

Stationary tabletop means a tabletop which, when assembled for use, is incapable of movement with respect to its supporting structure within the plane of the tabletop.

Technique factors means the following conditions of operation:

(1) For capacitor energy storage equipment, peak tube potential in kilovolts (kV) and quantity of charge in milliampere-seconds (mAs);

(2) For field emission equipment rated for pulsed operation, peak tube potential in kV and number of x-ray pulses;

(3) For CT equipment designed for pulsed operation, peak tube potential in kV, scan time in seconds, and either tube current in milliamperes (mA), x-ray pulse width in seconds, and the number of x-ray pulses per scan, or the product of the tube current, x-ray pulse width, and the number of x-ray pulses in mAs;

(4) For CT equipment not designed for pulsed operation, peak tube potential in kV, and either tube current in mA and scan time in seconds, or the product of tube current and exposure time in mAs and the scan time when the scan time and exposure time are equivalent; and

(5) For all other equipment, peak tube potential in kV, and either tube current in mA and exposure time in seconds, or the product of tube current and exposure time in mAs.

Tomogram means the depiction of the x-ray attenuation properties of a section through a body.

Tube means an x-ray tube, unless otherwise specified.

Tube housing assembly means the tube housing with tube installed. It includes high-voltage and/or filament transformers and other appropriate elements when they are contained within the tube housing.

Tube rating chart means the set of curves which specify the rated limits of operation of the tube in terms of the technique factors.

Useful beam means the radiation which passes through the tube housing port and the aperture of the beam-limiting device when the exposure switch or timer is activated.

Variable-aperture beam-limiting device means a beam-limiting device which has the capacity for stepless

adjustment of the x-ray field size at a given SID.

Visible area means the portion of the input surface of the image receptor over which incident x-ray photons are producing a visible image.

X-ray control means a device which controls input power to the x-ray high-voltage generator and/or the x-ray tube. It includes equipment such as timers, phototimers, automatic brightness stabilizers, and similar devices, which control the technique factors of an x-ray exposure.

X-ray equipment means an x-ray system, subsystem, or component thereof. Types of x-ray equipment are as follows:

(1) *Mobile x-ray equipment* means x-ray equipment mounted on a permanent base with wheels and/or casters for moving while completely assembled;

(2) *Portable x-ray equipment* means x-ray equipment designed to be hand-carried; and

(3) *Stationary x-ray equipment means* x-ray equipment which is installed in a fixed location.

X-ray field means that area of the intersection of the useful beam and any one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the AKR is one-fourth of the maximum in the intersection.

X-ray high-voltage generator means a device which transforms electrical energy from the potential supplied by the x-ray control to the tube operating potential. The device may also include means for transforming alternating current to direct current, filament transformers for the x-ray tube(s), high-voltage switches, electrical protective devices, and other appropriate elements.

X-ray subsystem means any combination of two or more components of an x-ray system for which there are requirements specified in this section and §§ 1020.31 and 1020.32.

X-ray system means an assemblage of components for the controlled production of x-rays. It includes minimally an x-ray high-voltage generator, an x-ray control, a tube housing assembly, a beam-limiting device, and the necessary supporting structures. Additional components which function with the system are considered integral parts of the system.

X-ray table means a patient support device with its patient support structure (tabletop) interposed between the patient and the image receptor during radiography and/or fluoroscopy. This includes, but is not limited to, any stretcher equipped with a radiolucent panel and any table equipped with a cassette tray (or bucky), cassette tunnel, fluoroscopic image receptor, or spot-film device beneath the tabletop.

X-ray tube means any electron tube which is designed for the conversion of electrical energy into x-ray energy.

(c) *Manufacturers' responsibility*. Manufacturers of products subject to §§ 1020.30 through 1020.33 shall certify that each of their products meet all applicable requirements when installed into a diagnostic x-ray system according to instructions. This certification shall be made under the format specified in § 1010.2 of this chapter. Manufacturers may certify a combination of two or more components if they obtain prior authorization in writing from the Director of the Office of Compliance of the Center for Devices and Radiological Health (CDRH). Manufacturers shall not be held responsible for noncompliance of their products if that noncompliance is due solely to the improper installation or assembly of that product by another person; however, manufacturers are responsible for providing assembly instructions adequate to assure compliance of their components with the applicable provisions of §§ 1020.30 through 1020.33.

(d) *Assemblers' responsibility*. An assembler who installs one or more components certified as required by paragraph (c) of this section shall install certified components that are of the type required by § 1020.31, 1020.32, or 1020.33 and shall assemble, install, adjust, and test the certified components according to the instructions of their respective manufacturers. Assemblers shall not be liable for noncompliance of a certified component if the assembly of that component was according to the component manufacturer's instruction.

(1) *Reports of assembly*. All assemblers who install certified components shall file a report of assembly, except as specified in paragraph (d)(2) of this section. The report will be construed as the assembler's certification and identification under §§ 1010.2 and 1010.3 of this chapter. The assembler shall affirm in the report that the manufacturer's instructions were followed in the assembly or that the certified components as assembled into the system meet all applicable requirements of §§ 1020.30 through 1020.33. All assembler reports must be on a form prescribed by the Director, CDRH. Completed reports must be submitted to the Director, the purchaser, and, where applicable, to the State agency responsible for radiation protection within 15 days following completion of the assembly.

(2) *Exceptions to reporting requirements*. Reports of assembly need not be submitted for any of the following:

(i) Reloaded or replacement tube housing assemblies that are reinstalled in or newly assembled into an existing x-ray system;

(ii) Certified accessory components that have been identified as such to CDRH in the report required under § 1002.10 of this chapter;

(iii) Repaired components, whether or not removed from the system and reinstalled during the course of repair, provided the original installation into the system was reported; or

(iv)(A) Components installed temporarily in an x-ray system in place of components removed temporarily for repair, provided the temporarily installed component is identified by a tag or label bearing the following information:

Temporarily Installed Component
This certified component has been assembled, installed, adjusted, and tested by me according to the instructions provided by the manufacturer.
Signature
Company Name
Street Address, P.O. Box
City, State, Zip Code
Date of Installation

(B) The replacement of the temporarily installed component by a component other than the component originally removed for repair shall be reported as specified in paragraph (d)(1) of this section.

(e) *Identification of x-ray components*. In addition to the identification requirements specified in § 1010.3 of this chapter, manufacturers of components subject to this section and §§ 1020.31, 1020.32, and 1020.33, except high-voltage generators contained within tube housings and beam-limiting devices that are integral parts of tube housings, shall permanently inscribe or affix thereon the model number and serial number of the product so that they are legible and accessible to view. The word ''model'' or ''type'' shall appear as part of the manufacturer's required identification of certified x-ray components. Where the certification of a system or subsystem, consisting of two or more components, has been authorized under paragraph (c) of this section, a single inscription, tag, or label bearing the model number and serial number may be used to identify the product.

(1) *Tube housing assemblies*. In a similar manner, manufacturers of tube housing assemblies shall also inscribe or affix thereon the name of the manufacturer, model number, and serial

number of the x-ray tube which the tube housing assembly incorporates.

(2) *Replacement of tubes*. Except as specified in paragraph (e)(3) of this section, the replacement of an x-ray tube in a previously manufactured tube housing assembly certified under paragraph (c) of this section constitutes manufacture of a new tube housing assembly, and the manufacturer is subject to the provisions of paragraph (e)(1) of this section. The manufacturer shall remove, cover, or deface any previously affixed inscriptions, tags, or labels that are no longer applicable.

(3) *Quick-change x-ray tubes*. The requirements of paragraph (e)(2) of this section shall not apply to tube housing assemblies designed and designated by their original manufacturer to contain quick change x-ray tubes. The manufacturer of quick-change x-ray tubes shall include with each replacement tube a label with the tube manufacturer's name, the model, and serial number of the x-ray tube. The manufacturer of the tube shall instruct the assembler who installs the new tube to attach the label to the tube housing assembly and to remove, cover, or deface the previously affixed inscriptions, tags, or labels that are described by the tube manufacturer as no longer applicable.

(f) [Reserved]

(g) *Information to be provided to assemblers*. Manufacturers of components listed in paragraph (a)(1) of this section shall provide to assemblers subject to paragraph (d) of this section and, upon request, to others at a cost not to exceed the cost of publication and distribution, instructions for assembly, installation, adjustment, and testing of such components adequate to assure that the products will comply with applicable provisions of this section and §§ 1020.31, 1020.32, and 1020.33, when assembled, installed, adjusted, and tested as directed. Such instructions shall include specifications of other components compatible with that to be installed when compliance of the system or subsystem depends on their compatibility. Such specifications may describe pertinent physical characteristics of the components and/or may list by manufacturer model number the components which are compatible. For x-ray controls and generators manufactured after May 3, 1994, manufacturers shall provide:

(1) A statement of the rated line voltage and the range of line-voltage regulation for operation at maximum line current;

(2) A statement of the maximum line current of the x-ray system based on the maximum input voltage and current characteristics of the tube housing assembly compatible with rated output voltage and rated output current characteristics of the x-ray control and associated high-voltage generator. If the rated input voltage and current characteristics of the tube housing assembly are not known by the manufacturer of the x-ray control and associated high-voltage generator, the manufacturer shall provide information necessary to allow the assembler to determine the maximum line current for the particular tube housing assembly(ies);

(3) A statement of the technique factors that constitute the maximum line current condition described in paragraph (g)(2) of this section.

(h) *Information to be provided to users*. Manufacturers of x-ray equipment shall provide to purchasers and, upon request, to others at a cost not to exceed the cost of publication and distribution, manuals or instruction sheets which shall include the following technical and safety information:

(1) *All x-ray equipment*. For x-ray equipment to which this section and §§ 1020.31, 1020.32, and 1020.33 are applicable, there shall be provided:

(i) Adequate instructions concerning any radiological safety procedures and precautions which may be necessary because of unique features of the equipment; and

(ii) A schedule of the maintenance necessary to keep the equipment in compliance with this section and §§ 1020.31, 1020.32, and 1020.33.

(2) *Tube housing assemblies*. For each tube housing assembly, there shall be provided:

(i) Statements of the leakage technique factors for all combinations of tube housing assemblies and beam-limiting devices for which the tube housing assembly manufacturer states compatibility, the minimum filtration permanently in the useful beam expressed as millimeters (mm) of aluminum equivalent, and the peak tube potential at which the aluminum equivalent was obtained;

(ii) Cooling curves for the anode and tube housing; and

(iii) Tube rating charts. If the tube is designed to operate from different types of x-ray high-voltage generators (such as single-phase self rectified, single-phase half-wave rectified, single-phase full-wave rectified, 3-phase 6-pulse, 3-phase 12-pulse, constant potential, capacitor energy storage) or under modes of operation such as alternate focal spot sizes or speeds of anode rotation which affect its rating, specific identification of the difference in ratings shall be noted.

(3) *X-ray controls and generators*. For the x-ray control and associated x-ray high-voltage generator, there shall be provided:

(i) A statement of the rated line voltage and the range of line-voltage regulation for operation at maximum line current;

(ii) A statement of the maximum line current of the x-ray system based on the maximum input voltage and output current characteristics of the tube housing assembly compatible with rated output voltage and rated current characteristics of the x-ray control and associated high-voltage generator. If the rated input voltage and current characteristics of the tube housing assembly are not known by the manufacturer of the x-ray control and associated high-voltage generator, the manufacturer shall provide necessary information to allow the purchaser to determine the maximum line current for his particular tube housing assembly(ies);

(iii) A statement of the technique factors that constitute the maximum line current condition described in paragraph (h)(3)(ii) of this section;

(iv) In the case of battery-powered generators, a specification of the minimum state of charge necessary for proper operation;

(v) Generator rating and duty cycle;

(vi) A statement of the maximum deviation from the preindication given by labeled technique factor control settings or indicators during any radiographic or CT exposure where the equipment is connected to a power supply as described in accordance with this paragraph. In the case of fixed technique factors, the maximum deviation from the nominal fixed value of each factor shall be stated;

(vii) A statement of the maximum deviation from the continuous indication of x-ray tube potential and current during any fluoroscopic exposure when the equipment is connected to a power supply as described in accordance with this paragraph; and

(viii) A statement describing the measurement criteria for all technique factors used in paragraphs (h)(3)(iii), (h)(3)(vi), and (h)(3)(vii) of this section; for example, the beginning and endpoints of exposure time measured with respect to a certain percentage of the voltage waveform.

(4) *Beam-limiting device*. For each variable-aperture beam-limiting device, there shall be provided;

(i) Leakage technique factors for all combinations of tube housing assemblies and beam-limiting devices

for which the beam-limiting device manufacturer states compatibility; and

(ii) A statement including the minimum aluminum equivalent of that part of the device through which the useful beam passes and including the x-ray tube potential at which the aluminum equivalent was obtained. When two or more filters are provided as part of the device, the statement shall include the aluminum equivalent of each filter.

(5) *Imaging system information.* For x-ray systems manufactured on or after June 10, 2006, that produce images using the fluoroscopic image receptor, the following information shall be provided in a separate, single section of the user's instruction manual or in a separate manual devoted to this information:

(i) For each mode of operation, a description of the mode and detailed instructions on how the mode is engaged and disengaged. The description of the mode shall identify those technique factors and system controls that are fixed or automatically adjusted by selection of the mode of operation, including the manner in which the automatic adjustment is controlled. This information shall include how the operator can recognize which mode of operation has been selected prior to initiation of x-ray production.

(ii) For each mode of operation, a descriptive example(s) of any specific clinical procedure(s) or imaging task(s) for which the mode is recommended or designed and how each mode should be used. Such recommendations do not preclude other clinical uses.

(6) *Displays of values of AKR and cumulative air kerma.* For fluoroscopic x-ray systems manufactured on or after June 10, 2006, the following shall be provided:

(i) A schedule of maintenance for any system instrumentation associated with the display of air kerma information necessary to maintain the displays of AKR and cumulative air kerma within the limits of allowed uncertainty specified by § 1020.32(k)(6) and, if the capability for user calibration of the display is provided, adequate instructions for such calibration;

(ii) Identification of the distances along the beam axis:

(A) From the focal spot to the isocenter, and

(B) From the focal spot to the reference location to which displayed values of AKR and cumulative air kerma refer according to § 1020.32(k)(4);

(iii) A rationale for specification of a reference irradiation location alternative to 15 cm from the isocenter toward the x-ray source along the beam axis when such alternative specification is made according to § 1020.32(k)(4)(ii).

(i) [Reserved]

(j) *Warning label.* The control panel containing the main power switch shall bear the warning statement, legible and accessible to view:

''Warning: This x-ray unit may be dangerous to patient and operator unless safe exposure factors, operating instructions and maintenance schedules are observed.''

(k) *Leakage radiation from the diagnostic source assembly.* The leakage radiation from the diagnostic source assembly measured at a distance of 1 meter in any direction from the source shall not exceed 0.88 milligray (mGy) air kerma (vice 100 milliroentgen (mR) exposure) in 1 hour when the x-ray tube is operated at the leakage technique factors. If the maximum rated peak tube potential of the tube housing assembly is greater than the maximum rated peak tube potential for the diagnostic source assembly, positive means shall be provided to limit the maximum x-ray tube potential to that of the diagnostic source assembly. Compliance shall be determined by measurements averaged over an area of 100 square cm with no linear dimension greater than 20 cm.

(l) *Radiation from components other than the diagnostic source assembly.* The radiation emitted by a component other than the diagnostic source assembly shall not exceed an air kerma of 18 microGy (vice 2 mR exposure) in 1 hour at 5 cm from any accessible surface of the component when it is operated in an assembled x-ray system under any conditions for which it was designed. Compliance shall be determined by measurements averaged over an area of 100 square cm with no linear dimension greater than 20 cm.

(m) *Beam quality*—(1) *Half-value layer (HVL).* The HVL of the useful beam for a given x-ray tube potential shall not be less than the appropriate value shown in table 1 in paragraph (m)(1) of this section under the heading ''Specified Dental Systems,'' for any dental x-ray system designed for use with intraoral image receptors and manufactured after December 1, 1980; under the heading ''I—Other X-Ray Systems,'' for any dental x-ray system designed for use with intraoral image receptors and manufactured before December 1, 1980, and all other x-ray systems subject to this section and manufactured before June 10, 2006; and under the heading ''II—Other X-Ray Systems,'' for all x-ray systems, except dental x-ray systems designed for use with intraoral image receptors, subject to this section and manufactured on or after June 10, 2006. If it is necessary to determine such HVL at an x-ray tube potential which is not listed in table 1 in paragraph (m)(1) of this section, linear interpolation or extrapolation may be made. Positive means[2] shall be provided to ensure that at least the minimum filtration needed to achieve the above beam quality requirements is in the useful beam during each exposure. Table 1 follows:

TABLE 1.

X-Ray Tube Voltage (kilovolt peak)		Minimum HVL (mm of aluminum)		
Designed Operating Range	Measured Operating Potential	Specified Dental Systems[1]	I—Other X-Ray Systems[2]	II—Other X-Ray Systems[3]
Below 51	30	1.5	0.3	0.3
	40	1.5	0.4	0.4
	50	1.5	0.5	0.5
51 to 70	51	1.5	1.2	1.3

[2] In the case of a system, which is to be operated with more than one thickness of filtration, this requirement can be met by a filter interlocked with the kilovoltage selector which will prevent x-ray emissions if the minimum required filtration is not in place.

TABLE 1.—Continued

X-Ray Tube Voltage (kilovolt peak)		Minimum HVL (mm of aluminum)		
Designed Operating Range	Measured Operating Potential	Specified Dental Systems[1]	I—Other X-Ray Systems[2]	II—Other X-Ray Systems[3]
	60	1.5	1.3	1.5
	70	1.5	1.5	1.8
Above 70	71	2.1	2.1	2.5
	80	2.3	2.3	2.9
	90	2.5	2.5	3.2
	100	2.7	2.7	3.6
	110	3.0	3.0	3.9
	120	3.2	3.2	4.3
	130	3.5	3.5	4.7
	140	3.8	3.8	5.0
	150	4.1	4.1	5.4

[1] Dental x-ray systems designed for use with intraoral image receptors and manufactured after December 1, 1980.
[2] Dental x-ray systems designed for use with intraoral image receptors and manufactured before or on December 1, 1980, and all other x-ray systems subject to this section and manufactured before June 10, 2006.
[3] All x-ray systems, except dental x-ray systems designed for use with intraoral image receptors, subject to this section and manufactured on or after June 10, 2006.

(2) *Optional filtration.* Fluoroscopic systems manufactured on or after June 10, 2006, incorporating an x-ray tube(s) with a continuous output of 1 kilowatt or more and an anode heat storage capacity of 1 million heat units or more shall provide the option of adding x-ray filtration to the diagnostic source assembly in addition to the amount needed to meet the HVL provisions of § 1020.30(m)(1). The selection of this additional x-ray filtration shall be either at the option of the user or automatic as part of the selected mode of operation. A means of indicating which combination of additional filtration is in the x-ray beam shall be provided.

(3) *Measuring compliance.* For capacitor energy storage equipment, compliance shall be determined with the maximum selectable quantity of charge per exposure.

(n) *Aluminum equivalent of material between patient and image receptor.* Except when used in a CT x-ray system, the aluminum equivalent of each of the items listed in table 2 in paragraph (n) of this section, which are used between the patient and image receptor, may not exceed the indicated limits. Compliance shall be determined by x-ray measurements made at a potential of 100 kilovolts peak and with an x-ray beam that has an HVL specified in table 1 in paragraph (m)(1) of this section for the potential. This requirement applies to front panel(s) of cassette holders and film changers provided by the manufacturer for patient support or for prevention of foreign object intrusions. It does not apply to screens and their associated mechanical support panels or grids. Table 2 follows:

TABLE 2.

Item	Maximum Aluminum Equivalent (millimeters)
1. Front panel(s) of cassette holders (total of all)	1.2
2. Front panel(s) of film changer (total of all)	1.2
3. Cradle	2.3
4. Tabletop, stationary, without articulated joints	1.2
5. Tabletop, movable, without articulated joint(s) (including stationary subtop)	1.7
6. Tabletop, with radiolucent panel having one articulated joint	1.7
7. Tabletop, with radiolucent panel having two or more articulated joints	2.3
8. Tabletop, cantilevered	2.3
9. Tabletop, radiation therapy simulator	5.0

(o) *Battery charge indicator*. On battery-powered generators, visual means shall be provided on the control panel to indicate whether the battery is in a state of charge adequate for proper operation.

(p) [Reserved]

(q) *Modification of certified diagnostic x-ray components and systems*. (1) Diagnostic x-ray components and systems certified in accordance with § 1010.2 of this chapter shall not be modified such that the component or system fails to comply with any applicable provision of this chapter unless a variance in accordance with § 1010.4 of this chapter or an exemption under section 534(a)(5) or 538(b) of the Federal Food, Drug, and Cosmetic Act has been granted.

(2) The owner of a diagnostic x-ray system who uses the system in a professional or commercial capacity may modify the system, provided the modification does not result in the failure of the system or component to comply with the applicable requirements of this section or of § 1020.31, 1020.32, or 1020.33. The owner who causes such modification need not submit the reports required by subpart B of part 1002 of this chapter, provided the owner records the date and the details of the modification in the system records and maintains this information, and provided the modification of the x-ray system does not result in a failure to comply with § 1020.31, 1020.32, or 1020.33.

■ 3. Revise § 1020.31 to read as follows:

§ 1020.31 Radiographic equipment.

The provisions of this section apply to equipment for radiography, except equipment for fluoroscopic imaging or for recording images from the fluoroscopic image receptor, or computed tomography x-ray systems manufactured on or after November 29, 1984.

(a) *Control and indication of technique factors*—(1) *Visual indication*. The technique factors to be used during an exposure shall be indicated before the exposure begins, except when automatic exposure controls are used, in which case the technique factors which are set prior to the exposure shall be indicated. On equipment having fixed technique factors, this requirement may be met by permanent markings. Indication of technique factors shall be visible from the operator's position except in the case of spot films made by the fluoroscopist.

(2) *Timers*. Means shall be provided to terminate the exposure at a preset time interval, a preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor.

(i) Except during serial radiography, the operator shall be able to terminate the exposure at any time during an exposure of greater than one-half second. Except during panoramic dental radiography, termination of exposure shall cause automatic resetting of the timer to its initial setting or to zero. It shall not be possible to make an exposure when the timer is set to a zero or off position if either position is provided.

(ii) During serial radiography, the operator shall be able to terminate the x-ray exposure(s) at any time, but means may be provided to permit completion of any single exposure of the series in process.

(3) *Automatic exposure controls*. When an automatic exposure control is provided:

(i) Indication shall be made on the control panel when this mode of operation is selected;

(ii) When the x-ray tube potential is equal to or greater than 51 kilovolts peak (kVp), the minimum exposure time for field emission equipment rated for pulsed operation shall be equal to or less than a time interval equivalent to two pulses and the minimum exposure time for all other equipment shall be equal to or less than 1/60 second or a time interval required to deliver 5 milliampere-seconds (mAs), whichever is greater;

(iii) Either the product of peak x-ray tube potential, current, and exposure time shall be limited to not more than 60 kilowatt-seconds (kWs) per exposure or the product of x-ray tube current and exposure time shall be limited to not more than 600 mAs per exposure, except when the x-ray tube potential is less than 51 kVp, in which case the product of x-ray tube current and exposure time shall be limited to not more than 2,000 mAs per exposure; and

(iv) A visible signal shall indicate when an exposure has been terminated at the limits described in paragraph (a)(3)(iii) of this section, and manual resetting shall be required before further automatically timed exposures can be made.

(4) *Accuracy*. Deviation of technique factors from indicated values shall not exceed the limits given in the information provided in accordance with § 1020.30(h)(3).

(b) *Reproducibility*. The following requirements shall apply when the equipment is operated on an adequate power supply as specified by the manufacturer in accordance with the requirements of § 1020.30(h)(3):

(1) *Coefficient of variation*. For any specific combination of selected technique factors, the estimated coefficient of variation of the air kerma shall be no greater than 0.05.

(2) *Measuring compliance*. Determination of compliance shall be based on 10 consecutive measurements taken within a time period of 1 hour. Equipment manufactured after September 5, 1978, shall be subject to the additional requirement that all variable controls for technique factors shall be adjusted to alternate settings and reset to the test setting after each measurement. The percent line-voltage regulation shall be determined for each measurement. All values for percent line-voltage regulation shall be within ±1 of the mean value for all measurements. For equipment having automatic exposure controls, compliance shall be determined with a sufficient thickness of attenuating material in the useful beam such that the technique factors can be adjusted to provide individual exposures of a minimum of 12 pulses on field emission equipment rated for pulsed operation or no less than one-tenth second per exposure on all other equipment.

(c) *Linearity*. The following requirements apply when the equipment is operated on a power supply as specified by the manufacturer in accordance with the requirements of § 1020.30(h)(3) for any fixed x-ray tube potential within the range of 40 percent to 100 percent of the maximum rated.

(1) *Equipment having independent selection of x-ray tube current (mA)*. The average ratios of air kerma to the indicated milliampere-seconds product (mGy/mAs) obtained at any two consecutive tube current settings shall not differ by more than 0.10 times their sum. This is: $|X_1 - X_2| \leq 0.10(X_1 + X_2)$; where X_1 and X_2 are the average mGy/mAs values obtained at each of two consecutive mAs selector settings or at two settings differing by no more than a factor of 2 where the mAs selector provides continuous selection.

(2) *Equipment having selection of x-ray tube current-exposure time product (mAs)*. For equipment manufactured after May 3, 1994, the average ratios of air kerma to the indicated milliampere-seconds product (mGy/mAs) obtained at any two consecutive mAs selector settings shall not differ by more than 0.10 times their sum. This is: $|X_1 - X_2| \leq 0.10\ (X_1 + X_2)$; where X_1 and X_2 are the average mGy/mAs values obtained at each of two consecutive mAs selector settings or at two settings differing by no more than a factor of 2 where the mAs selector provides continuous selection.

(3) *Measuring compliance.* Determination of compliance will be based on 10 exposures, made within 1 hour, at each of the two settings. These two settings may include any two focal spot sizes except where one is equal to or less than 0.45 mm and the other is greater than 0.45 mm. For purposes of this requirement, focal spot size is the focal spot size specified by the x-ray tube manufacturer. The percent line-voltage regulation shall be determined for each measurement. All values for percent line-voltage regulation at any one combination of technique factors shall be within ±1 of the mean value for all measurements at these technique factors.

(d) *Field limitation and alignment for mobile, portable, and stationary general purpose x-ray systems.* Except when spot-film devices are in service, mobile, portable, and stationary general purpose radiographic x-ray systems shall meet the following requirements:

(1) *Variable x-ray field limitation.* A means for stepless adjustment of the size of the x-ray field shall be provided. Each dimension of the minimum field size at an SID of 100 centimeters (cm) shall be equal to or less than 5 cm.

(2) *Visual definition.* (i) Means for visually defining the perimeter of the x-ray field shall be provided. The total misalignment of the edges of the visually defined field with the respective edges of the x-ray field along either the length or width of the visually defined field shall not exceed 2 percent of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the x-ray beam.

(ii) When a light localizer is used to define the x-ray field, it shall provide an average illuminance of not less than 160 lux (15 footcandles) at 100 cm or at the maximum SID, whichever is less. The average illuminance shall be based on measurements made in the approximate center of each quadrant of the light field. Radiation therapy simulation systems are exempt from this requirement.

(iii) The edge of the light field at 100 cm or at the maximum SID, whichever is less, shall have a contrast ratio, corrected for ambient lighting, of not less than 4 in the case of beam-limiting devices designed for use on stationary equipment, and a contrast ratio of not less than 3 in the case of beam-limiting devices designed for use on mobile and portable equipment. The contrast ratio is defined as I_1/I_2, where I_1 is the illuminance 3 mm from the edge of the light field toward the center of the field; and I_2 is the illuminance 3 mm from the edge of the light field away from the center of the field. Compliance shall be determined with a measuring aperture of 1 mm.

(e) *Field indication and alignment on stationary general purpose x-ray equipment.* Except when spot-film devices are in service, stationary general purpose x-ray systems shall meet the following requirements in addition to those prescribed in paragraph (d) of this section:

(1) Means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor, to align the center of the x-ray field with respect to the center of the image receptor to within 2 percent of the SID, and to indicate the SID to within 2 percent;

(2) The beam-limiting device shall numerically indicate the field size in the plane of the image receptor to which it is adjusted;

(3) Indication of field size dimensions and SIDs shall be specified in centimeters and/or inches and shall be such that aperture adjustments result in x-ray field dimensions in the plane of the image receptor which correspond to those indicated by the beam-limiting device to within 2 percent of the SID when the beam axis is indicated to be perpendicular to the plane of the image receptor; and

(4) Compliance measurements will be made at discrete SIDs and image receptor dimensions in common clinical use (such as SIDs of 100, 150, and 200 cm and/or 36, 40, 48, and 72 inches and nominal image receptor dimensions of 13, 18, 24, 30, 35, 40, and 43 cm and/or 5, 7, 8, 9, 10, 11, 12, 14, and 17 inches) or at any other specific dimensions at which the beam-limiting device or its associated diagnostic x-ray system is uniquely designed to operate.

(f) *Field limitation on radiographic x-ray equipment other than general purpose radiographic systems*—(1) *Equipment for use with intraoral image receptors.* Radiographic equipment designed for use with an intraoral image receptor shall be provided with means to limit the x-ray beam such that:

(i) If the minimum source-to-skin distance (SSD) is 18 cm or more, the x-ray field at the minimum SSD shall be containable in a circle having a diameter of no more than 7 cm; and

(ii) If the minimum SSD is less than 18 cm, the x-ray field at the minimum SSD shall be containable in a circle having a diameter of no more than 6 cm.

(2) *X-ray systems designed for one image receptor size.* Radiographic equipment designed for only one image receptor size at a fixed SID shall be provided with means to limit the field at the plane of the image receptor to dimensions no greater than those of the image receptor, and to align the center of the x-ray field with the center of the image receptor to within 2 percent of the SID, or shall be provided with means to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor.

(3) *Systems designed for mammography*—(i) Radiographic systems designed only for mammography and general purpose radiography systems, when special attachments for mammography are in service, manufactured on or after November 1, 1977, and before September 30, 1999, shall be provided with means to limit the useful beam such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor at any designated SID except the edge of the image receptor designed to be adjacent to the chest wall where the x-ray field may not extend beyond this edge by more than 2 percent of the SID. This requirement can be met with a system that performs as prescribed in paragraphs (f)(4)(i), (f)(4)(ii), and (f)(4)(iii) of this section. When the beam-limiting device and image receptor support device are designed to be used to immobilize the breast during a mammographic procedure and the SID may vary, the SID indication specified in paragraphs (f)(4)(ii) and (f)(4)(iii) of this section shall be the maximum SID for which the beam-limiting device or aperture is designed.

(ii) Mammographic beam-limiting devices manufactured on or after September 30, 1999, shall be provided with a means to limit the useful beam such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor by more than 2 percent of the SID. This requirement can be met with a system that performs as prescribed in paragraphs (f)(4)(i), (f)(4)(ii), and (f)(4)(iii) of this section. For systems that allow changes in the SID, the SID indication specified in paragraphs (f)(4)(ii) and (f)(4)(iii) of this section shall be the maximum SID for which the beam-limiting device or aperture is designed.

(iii) Each image receptor support device manufactured on or after November 1, 1977, intended for installation on a system designed for mammography shall have clear and permanent markings to indicate the maximum image receptor size for which it is designed.

(4) *Other x-ray systems*. Radiographic systems not specifically covered in paragraphs (d), (e), (f)(2), (f)(3), and (h) of this section and systems covered in paragraph (f)(1) of this section, which are also designed for use with extraoral image receptors and when used with an extraoral image receptor, shall be provided with means to limit the x-ray field in the plane of the image receptor so that such field does not exceed each dimension of the image receptor by more than 2 percent of the SID, when the axis of the x-ray beam is perpendicular to the plane of the image receptor. In addition, means shall be provided to align the center of the x-ray field with the center of the image receptor to within 2 percent of the SID, or means shall be provided to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor. These requirements may be met with:

(i) A system which performs in accordance with paragraphs (d) and (e) of this section; or when alignment means are also provided, may be met with either;

(ii) An assortment of removable, fixed-aperture, beam-limiting devices sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed. Each such device shall have clear and permanent markings to indicate the image receptor size and SID for which it is designed; or

(iii) A beam-limiting device having multiple fixed apertures sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed. Permanent, clearly legible markings shall indicate the image receptor size and SID for which each aperture is designed and shall indicate which aperture is in position for use.

(g) *Positive beam limitation (PBL)*. The requirements of this paragraph shall apply to radiographic systems which contain PBL.

(1) *Field size*. When a PBL system is provided, it shall prevent x-ray production when:

(i) Either the length or width of the x-ray field in the plane of the image receptor differs from the corresponding image receptor dimension by more than 3 percent of the SID; or

(ii) The sum of the length and width differences as stated in paragraph (g)(1)(i) of this section without regard to sign exceeds 4 percent of the SID.

(iii) The beam limiting device is at an SID for which PBL is not designed for sizing.

(2) *Conditions for PBL*. When provided, the PBL system shall function as described in paragraph (g)(1) of this section whenever all the following conditions are met:

(i) The image receptor is inserted into a permanently mounted cassette holder;

(ii) The image receptor length and width are less than 50 cm;

(iii) The x-ray beam axis is within ±3 degrees of vertical and the SID is 90 cm to 130 cm inclusive; or the x-ray beam axis is within ±3 degrees of horizontal and the SID is 90 cm to 205 cm inclusive;

(iv) The x-ray beam axis is perpendicular to the plane of the image receptor to within ±3 degrees; and

(v) Neither tomographic nor stereoscopic radiography is being performed.

(3) *Measuring compliance*. Compliance with the requirements of paragraph (g)(1) of this section shall be determined when the equipment indicates that the beam axis is perpendicular to the plane of the image receptor and the provisions of paragraph (g)(2) of this section are met. Compliance shall be determined no sooner than 5 seconds after insertion of the image receptor.

(4) *Operator initiated undersizing*. The PBL system shall be capable of operation such that, at the discretion of the operator, the size of the field may be made smaller than the size of the image receptor through stepless adjustment of the field size. Each dimension of the minimum field size at an SID of 100 cm shall be equal to or less than 5 cm. Return to PBL function as described in paragraph (g)(1) of this section shall occur automatically upon any change of image receptor size or SID.

(5) *Override of PBL*. A capability may be provided for overriding PBL in case of system failure and for servicing the system. This override may be for all SIDs and image receptor sizes. A key shall be required for any override capability that is accessible to the operator. It shall not be possible to remove the key while PBL is overridden. Each such key switch or key shall be clearly and durably labeled as follows:

For X-ray Field Limitation System Failure
The override capability is considered accessible to the operator if it is referenced in the operator's manual or in other material intended for the operator or if its location is such that the operator would consider it part of the operational controls.

(h) *Field limitation and alignment for spot-film devices*. The following requirements shall apply to spot-film devices, except when the spot-film device is provided for use with a radiation therapy simulation system:

(1) Means shall be provided between the source and the patient for adjustment of the x-ray field size in the plane of the image receptor to the size of that portion of the image receptor which has been selected on the spot-film selector. Such adjustment shall be accomplished automatically when the x-ray field size in the plane of the image receptor is greater than the selected portion of the image receptor. If the x-ray field size is less than the size of the selected portion of the image receptor, the field size shall not open automatically to the size of the selected portion of the image receptor unless the operator has selected that mode of operation.

(2) Neither the length nor the width of the x-ray field in the plane of the image receptor shall differ from the corresponding dimensions of the selected portion of the image receptor by more than 3 percent of the SID when adjusted for full coverage of the selected portion of the image receptor. The sum, without regard to sign, of the length and width differences shall not exceed 4 percent of the SID. On spot-film devices manufactured after February 25, 1978, if the angle between the plane of the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor, and compliance shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.

(3) The center of the x-ray field in the plane of the image receptor shall be aligned with the center of the selected portion of the image receptor to within 2 percent of the SID.

(4) Means shall be provided to reduce the x-ray field size in the plane of the image receptor to a size smaller than the selected portion of the image receptor such that:

(i) For spot-film devices used on fixed-SID fluoroscopic systems which are not required to, and do not provide stepless adjustment of the x-ray field, the minimum field size, at the greatest SID, does not exceed 125 square cm; or

(ii) For spot-film devices used on fluoroscopic systems that have a variable SID and/or stepless adjustment of the field size, the minimum field size, at the greatest SID, shall be containable in a square of 5 cm by 5 cm.

(5) A capability may be provided for overriding the automatic x-ray field size adjustment in case of system failure. If it is so provided, a signal visible at the fluoroscopist's position shall indicate whenever the automatic x-ray field size adjustment override is engaged. Each

such system failure override switch shall be clearly labeled as follows:
For X-ray Field Limitation System Failure

(i) *Source-skin distance*—(1) X-ray systems designed for use with an intraoral image receptor shall be provided with means to limit the source-skin distance to not less than:

(i) Eighteen cm if operable above 50 kVp; or

(ii) Ten cm if not operable above 50 kVp.

(2) Mobile and portable x-ray systems other than dental shall be provided with means to limit the source-skin distance to not less than 30 cm.

(j) *Beam-on indicators*. The x-ray control shall provide visual indication whenever x-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.

(k) *Multiple tubes*. Where two or more radiographic tubes are controlled by one exposure switch, the tube or tubes which have been selected shall be clearly indicated before initiation of the exposure. This indication shall be both on the x-ray control and at or near the tube housing assembly which has been selected.

(l) *Radiation from capacitor energy storage equipment*. Radiation emitted from the x-ray tube shall not exceed:

(1) An air kerma of 0.26 microGy (vice 0.03 mR exposure) in 1 minute at 5 cm from any accessible surface of the diagnostic source assembly, with the beam-limiting device fully open, the system fully charged, and the exposure switch, timer, or any discharge mechanism not activated. Compliance shall be determined by measurements averaged over an area of 100 square cm, with no linear dimension greater than 20 cm; and

(2) An air kerma of 0.88 mGy (vice 100 mR exposure) in 1 hour at 100 cm from the x-ray source, with the beam-limiting device fully open, when the system is discharged through the x-ray tube either manually or automatically by use of a discharge switch or deactivation of the input power. Compliance shall be determined by measurements of the maximum air kerma per discharge multiplied by the total number of discharges in 1 hour (duty cycle). The measurements shall be averaged over an area of 100 square cm with no linear dimension greater than 20 cm.

(m) *Primary protective barrier for mammography x-ray systems*—(1) For x-ray systems manufactured after September 5, 1978, and before September 30, 1999, which are designed only for mammography, the transmission of the primary beam through any image receptor support provided with the system shall be limited such that the air kerma 5 cm from any accessible surface beyond the plane of the image receptor supporting device does not exceed 0.88 microGy (vice 0.1 mR exposure) for each activation of the tube.

(2) For mammographic x-ray systems manufactured on or after September 30, 1999:

(i) At any SID where exposures can be made, the image receptor support device shall provide a primary protective barrier that intercepts the cross section of the useful beam along every direction except at the chest wall edge.

(ii) The x-ray system shall not permit exposure unless the appropriate barrier is in place to intercept the useful beam as required in paragraph (m)(2)(i) of this section.

(iii) The transmission of the useful beam through the primary protective barrier shall be limited such that the air kerma 5 cm from any accessible surface beyond the plane of the primary protective barrier does not exceed 0.88 microGy (vice 0.1 mR exposure) for each activation of the tube.

(3) Compliance with the requirements of paragraphs (m)(1) and (m)(2)(iii) of this section for transmission shall be determined with the x-ray system operated at the minimum SID for which it is designed, at the maximum rated peak tube potential, at the maximum rated product of x-ray tube current and exposure time (mAs) for the maximum rated peak tube potential, and by measurements averaged over an area of 100 square cm with no linear dimension greater than 20 cm. The sensitive volume of the radiation measuring instrument shall not be positioned beyond the edge of the primary protective barrier along the chest wall side.

■ 4. Revise § 1020.32 to read as follows:

§ 1020.32 Fluoroscopic equipment.

The provisions of this section apply to equipment for fluoroscopic imaging or for recording images from the fluoroscopic image receptor, except computed tomography x-ray systems manufactured on or after November 29, 1984.

(a) *Primary protective barrier*—(1) *Limitation of useful beam*. The fluoroscopic imaging assembly shall be provided with a primary protective barrier which intercepts the entire cross section of the useful beam at any SID. The x-ray tube used for fluoroscopy shall not produce x-rays unless the barrier is in position to intercept the entire useful beam. The AKR due to transmission through the barrier with the attenuation block in the useful beam combined with radiation from the fluoroscopic image receptor shall not exceed 3.34×10^{-3} percent of the entrance AKR, at a distance of 10 cm from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor. Radiation therapy simulation systems shall be exempt from this requirement provided the systems are intended only for remote control operation and the manufacturer sets forth instructions for assemblers with respect to control location as part of the information required in § 1020.30(g). Additionally, the manufacturer shall provide to users, under § 1020.30(h)(1)(i), precautions concerning the importance of remote control operation.

(2) *Measuring compliance*. The AKR shall be measured in accordance with paragraph (d) of this section. The AKR due to transmission through the primary barrier combined with radiation from the fluoroscopic image receptor shall be determined by measurements averaged over an area of 100 square cm with no linear dimension greater than 20 cm. If the source is below the tabletop, the measurement shall be made with the input surface of the fluoroscopic imaging assembly positioned 30 cm above the tabletop. If the source is above the tabletop and the SID is variable, the measurement shall be made with the end of the beam-limiting device or spacer as close to the tabletop as it can be placed, provided that it shall not be closer than 30 cm. Movable grids and compression devices shall be removed from the useful beam during the measurement. For all measurements, the attenuation block shall be positioned in the useful beam 10 cm from the point of measurement of entrance AKR and between this point and the input surface of the fluoroscopic imaging assembly.

(b) *Field limitation*—(1) *Angulation*. For fluoroscopic equipment manufactured after February 25, 1978, when the angle between the image receptor and the beam axis of the x-ray beam is variable, means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor. Compliance with paragraphs (b)(4) and (b)(5) of this section shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.

(2) *Further means for limitation*. Means shall be provided to permit further limitation of the x-ray field to sizes smaller than the limits of paragraphs (b)(4) and (b)(5). Beam-limiting devices manufactured after May 22, 1979, and incorporated in equipment with a variable SID and/or

the capability of a visible area of greater than 300 square cm, shall be provided with means for stepless adjustment of the x-ray field. Equipment with a fixed SID and the capability of a visible area of no greater than 300 square cm shall be provided with either stepless adjustment of the x-ray field or with a means to further limit the x-ray field size at the plane of the image receptor to 125 square cm or less. Stepless adjustment shall, at the greatest SID, provide continuous field sizes from the maximum obtainable to a field size containable in a square of 5 cm by 5 cm. This paragraph does not apply to non-image-intensified fluoroscopy.

(3) *Non-image-intensified fluoroscopy*. The x-ray field produced by non-image-intensified fluoroscopic equipment shall not extend beyond the entire visible area of the image receptor. Means shall be provided for stepless adjustment of field size. The minimum field size, at the greatest SID, shall be containable in a square of 5 cm by 5 cm.

(4) *Fluoroscopy and radiography using the fluoroscopic imaging assembly with inherently circular image receptors*. (i) For fluoroscopic equipment manufactured before June 10, 2006, other than radiation therapy simulation systems, the following applies:

(A) Neither the length nor the width of the x-ray field in the plane of the image receptor shall exceed that of the visible area of the image receptor by more than 3 percent of the SID. The sum of the excess length and the excess width shall be no greater than 4 percent of the SID.

(B) For rectangular x-ray fields used with circular image receptors, the error in alignment shall be determined along the length and width dimensions of the x-ray field which pass through the center of the visible area of the image receptor.

(ii) For fluoroscopic equipment manufactured on or after June 10, 2006, other than radiation therapy simulation systems, the maximum area of the x-ray field in the plane of the image receptor shall conform with one of the following requirements:

(A) When any linear dimension of the visible area of the image receptor measured through the center of the visible area is less than or equal to 34 cm in any direction, at least 80 percent of the area of the x-ray field overlaps the visible area of the image receptor, or

(B) When any linear dimension of the visible area of the image receptor measured through the center of the visible area is greater than 34 cm in any direction, the x-ray field measured along the direction of greatest misalignment with the visible area of the image receptor does not extend beyond the edge of the visible area of the image receptor by more than 2 cm.

(5) *Fluoroscopy and radiography using the fluoroscopic imaging assembly with inherently rectangular image receptors*. For x-ray systems manufactured on or after June 10, 2006, the following applies:

(i) Neither the length nor the width of the x-ray field in the plane of the image receptor shall exceed that of the visible area of the image receptor by more than 3 percent of the SID. The sum of the excess length and the excess width shall be no greater than 4 percent of the SID.

(ii) The error in alignment shall be determined along the length and width dimensions of the x-ray field which pass through the center of the visible area of the image receptor.

(6) *Override capability*. If the fluoroscopic x-ray field size is adjusted automatically as the SID or image receptor size is changed, a capability may be provided for overriding the automatic adjustment in case of system failure. If it is so provided, a signal visible at the fluoroscopist's position shall indicate whenever the automatic field adjustment is overridden. Each such system failure override switch shall be clearly labeled as follows:

For X-ray Field Limitation System Failure

(c) *Activation of tube*. X-ray production in the fluoroscopic mode shall be controlled by a device which requires continuous pressure by the operator for the entire time of any exposure. When recording serial radiographic images from the fluoroscopic image receptor, the operator shall be able to terminate the x-ray exposure(s) at any time, but means may be provided to permit completion of any single exposure of the series in process.

(d) *Air kerma rates*. For fluoroscopic equipment, the following requirements apply:

(1) *Fluoroscopic equipment manufactured before May 19, 1995*—(i) Equipment provided with automatic exposure rate control (AERC) shall not be operable at any combination of tube potential and current that will result in an AKR in excess of 88 mGy per minute (vice 10 R/min exposure rate) at the measurement point specified in § 1020.32(d)(3), except as specified in § 1020.32(d)(1)(v).

(ii) Equipment provided without AERC shall not be operable at any combination of tube potential and current that will result in an AKR in excess of 44 mGy per minute (vice 5 R/min exposure rate) at the measurement point specified in § 1020.32(d)(3), except as specified in § 1020.32(d)(1)(v).

(iii) Equipment provided with both an AERC mode and a manual mode shall not be operable at any combination of tube potential and current that will result in an AKR in excess of 88 mGy per minute (vice 10 R/min exposure rate) in either mode at the measurement point specified in § 1020.32(d)(3), except as specified in § 1020.32(d)(1)(v).

(iv) Equipment may be modified in accordance with § 1020.30(q) to comply with § 1020.32(d)(2). When the equipment is modified, it shall bear a label indicating the date of the modification and the statement:

Modified to comply with 21 CFR 1020.32(h)(2).

(v) Exceptions:

(A) During recording of fluoroscopic images, or

(B) When a mode of operation has an optional high-level control, in which case that mode shall not be operable at any combination of tube potential and current that will result in an AKR in excess of the rates specified in § 1020.32(d)(1)(i), (d)(1)(ii), or (d)(1)(iii) at the measurement point specified in § 1020.32(d)(3), unless the high-level control is activated. Special means of activation of high-level controls shall be required. The high-level control shall be operable only when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high-level control is being employed.

(2) *Fluoroscopic equipment manufactured on or after May 19, 1995*—(i) Shall be equipped with AERC if operable at any combination of tube potential and current that results in an AKR greater than 44 mGy per minute (vice 5 R/min exposure rate) at the measurement point specified in § 1020.32(d)(3). Provision for manual selection of technique factors may be provided.

(ii) Shall not be operable at any combination of tube potential and current that will result in an AKR in excess of 88 mGy per minute (vice 10 R/min exposure rate) at the measurement point specified in § 1020.32(d)(3), except as specified in § 1020.32(d)(2)(iii):

(iii) Exceptions:

(A) For equipment manufactured prior to June 10, 2006, during the recording of images from a fluoroscopic image receptor using photographic film or a video camera when the x-ray source is operated in a pulsed mode.

(B) For equipment manufactured on or after June 10, 2006, during the recording of images from the fluoroscopic image receptor for the purpose of providing the user with a recorded image(s) after termination of

the exposure. Such recording does not include images resulting from a last-image-hold feature that are not recorded.

(C) When a mode of operation has an optional high-level control and the control is activated, in which case the equipment shall not be operable at any combination of tube potential and current that will result in an AKR in excess of 176 mGy per minute (vice 20 R/min exposure rate) at the measurement point specified in § 1020.32(d)(3). Special means of activation of high-level controls shall be required. The high-level control shall be operable only when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high-level control is being employed.

(3) *Measuring compliance*. Compliance with paragraph (d) of this section shall be determined as follows:

(i) If the source is below the x-ray table, the AKR shall be measured at 1 cm above the tabletop or cradle.

(ii) If the source is above the x-ray table, the AKR shall be measured at 30 cm above the tabletop with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement.

(iii) In a C-arm type of fluoroscope, the AKR shall be measured at 30 cm from the input surface of the fluoroscopic imaging assembly, with the source positioned at any available SID, provided that the end of the beam-limiting device or spacer is no closer than 30 cm from the input surface of the fluoroscopic imaging assembly.

(iv) In a C-arm type of fluoroscope having an SID less than 45 cm, the AKR shall be measured at the minimum SSD.

(v) In a lateral type of fluoroscope, the air kerma rate shall be measured at a point 15 cm from the centerline of the x-ray table and in the direction of the x-ray source with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement. If the tabletop is movable, it shall be positioned as closely as possible to the lateral x-ray source, with the end of the beam-limiting device or spacer no closer than 15 cm to the centerline of the x-ray table.

(4) *Exemptions*. Fluoroscopic radiation therapy simulation systems are exempt from the requirements set forth in paragraph (d) of this section.

(e) [Reserved]

(f) *Indication of potential and current*. During fluoroscopy and cinefluorography, x-ray tube potential and current shall be continuously indicated. Deviation of x-ray tube potential and current from the indicated values shall not exceed the maximum deviation as stated by the manufacturer in accordance with § 1020.30(h)(3).

(g) *Source-skin distance*. (1) Means shall be provided to limit the source-skin distance to not less than 38 cm on stationary fluoroscopes and to not less than 30 cm on mobile and portable fluoroscopes. In addition, for fluoroscopes intended for specific surgical application that would be prohibited at the source-skin distances specified in this paragraph, provisions may be made for operation at shorter source-skin distances but in no case less than 20 cm. When provided, the manufacturer must set forth precautions with respect to the optional means of spacing, in addition to other information as required in § 1020.30(h).

(2) For stationary, mobile, or portable C-arm fluoroscopic systems manufactured on or after June 10, 2006, having a maximum source-image receptor distance of less than 45 cm, means shall be provided to limit the source-skin distance to not less than 19 cm. Such systems shall be labeled for extremity use only. In addition, for those systems intended for specific surgical application that would be prohibited at the source-skin distances specified in this paragraph, provisions may be made for operation at shorter source-skin distances but in no case less than 10 cm. When provided, the manufacturer must set forth precautions with respect to the optional means of spacing, in addition to other information as required in § 1020.30(h).

(h) *Fluoroscopic irradiation time, display, and signal*. (1)(i) Fluoroscopic equipment manufactured before June 10, 2006, shall be provided with means to preset the cumulative irradiation time of the fluoroscopic tube. The maximum cumulative time of the timing device shall not exceed 5 minutes without resetting. A signal audible to the fluoroscopist shall indicate the completion of any preset cumulative irradiation-time. Such signal shall continue to sound while x-rays are produced until the timing device is reset. Fluoroscopic equipment may be modified in accordance with § 1020.30(q) to comply with the requirements of § 1020.32(h)(2). When the equipment is modified, it shall bear a label indicating the statement: Modified to comply with 21 CFR 1020.32(h)(2).

(ii) As an alternative to the requirements of this paragraph, radiation therapy simulation systems may be provided with a means to indicate the total cumulative exposure time during which x-rays were produced, and which is capable of being reset between x-ray examinations.

(2) For x-ray controls manufactured on or after June 10, 2006, there shall be provided for each fluoroscopic tube:

(i) A display of the fluoroscopic irradiation time at the fluoroscopist's working position. This display shall function independently of the audible signal described in § 1020.32(h)(2)(ii). The following requirements apply:

(A) When the x-ray tube is activated, the fluoroscopic irradiation time in minutes and tenths of minutes shall be continuously displayed and updated at least once every 6 seconds.

(B) The fluoroscopic irradiation time shall also be displayed within 6 seconds of termination of an exposure and remain displayed until reset.

(C) Means shall be provided to reset the display to zero prior to the beginning of a new examination or procedure.

(ii) A signal audible to the fluoroscopist shall sound for each passage of 5 minutes of fluoroscopic irradiation time during an examination or procedure. The signal shall sound until manually reset or, if automatically reset, for at least 2 second.

(i) *Mobile and portable fluoroscopes*. In addition to the other requirements of this section, mobile and portable fluoroscopes shall provide an image receptor incorporating more than a simple fluorescent screen.

(j) *Display of last-image-hold (LIH)*. Fluoroscopic equipment manufactured on or after June 10, 2006, shall be equipped with means to display LIH image following termination of the fluoroscopic exposure.

(1) For an LIH image obtained by retaining pretermination fluoroscopic images, if the number of images and method of combining images are selectable by the user, the selection shall be indicated prior to initiation of the fluoroscopic exposure.

(2) For an LIH image obtained by initiating a separate radiographic-like exposure at the termination of fluoroscopic imaging, the techniques factors for the LIH image shall be selectable prior to the fluoroscopic exposure, and the combination selected shall be indicated prior to initiation of the fluoroscopic exposure.

(3) Means shall be provided to clearly indicate to the user whether a displayed image is the LIH radiograph or fluoroscopy. Display of the LIH radiograph shall be replaced by the fluoroscopic image concurrently with re-initiation of fluoroscopic exposure, unless separate displays are provided for the LIH radiograph and fluoroscopic images.

(4) The predetermined or selectable options for producing the LIH radiograph shall be described in the information required by § 1020.30(h). The information shall include a description of any technique factors applicable for the selected option and the impact of the selectable options on image characteristics and the magnitude of radiation emissions.

(k) *Displays of values of AKR and cumulative air kerma.* Fluoroscopic equipment manufactured on or after June 10, 2006, shall display at the fluoroscopist's working position the AKR and cumulative air kerma. The following requirements apply for each x-ray tube used during an examination or procedure:

(1) When the x-ray tube is activated and the number of images produced per unit time is greater than six images per second, the AKR in mGy/min shall be continuously displayed and updated at least once every second.

(2) The cumulative air kerma in units of mGy shall be displayed either within 5 seconds of termination of an exposure or displayed continuously and updated at least once every 5 seconds.

(3) The display of the AKR shall be clearly distinguishable from the display of the cumulative air kerma.

(4) The AKR and cumulative air kerma shall represent the value for conditions of free-in-air irradiation at one of the following reference locations specified according to the type of fluoroscope. The reference location shall be identified and described specifically in the information provided to users according to § 1020.30(h)(6)(iii).

(i) For fluoroscopes with x-ray source below the x-ray table, x-ray source above the table, or of lateral type, the reference locations shall be the respective locations specified in § 1020.32(d)(3)(i), (d)(3)(ii), or (d)(3)(v) for measuring compliance with air-kerma rate limits.

(ii) For C-arm fluoroscopes, the reference location shall be 15 cm from the isocenter toward the x-ray source along the beam axis. Alternatively, the reference location shall be at a point specified by the manufacturer to represent the location of the intersection of the x-ray beam with the patient's skin.

(5) Means shall be provided to reset to zero the display of cumulative air kerma prior to the commencement of a new examination or procedure.

(6) The displayed AKR and cumulative air kerma shall not deviate from the actual values by more than ±35 percent over the range of 6 mGy/min and 100 mGy to the maximum indication of AKR and cumulative air kerma, respectively. Compliance shall be determined with an irradiation time greater than 3 seconds.

■ 5. Amend § 1020.33 by revising paragraph (h)(2) to read as follows:

§ 1020.33 Computed tomography (CT) equipment.

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(h) * * *

(2) For systems that allow high voltage to be applied to the x-ray tube continuously and that control the emission of x-ray with a shutter, the radiation emitted may not exceed 0.88 milligray (vice 100 milliroentgen exposure) in 1 hour at any point 5 cm outside the external surface of the housing of the scanning mechanism when the shutter is closed. Compliance shall be determined by measurements average over an area of 100 square cm with no linear dimension greater than 20 cm.

* * * * *

Dated: May 31, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–11480 Filed 6–7–05; 10:51 am]

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Federal Register

Friday,
June 10, 2005

Part IV

Department of Housing and Urban Development

Notice of Draft Outcome Performance Measurement System for Community Planning and Development Formula Grant Programs; Request for Comments; Notice

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4970–N–01; HUD–2005–0011]

Notice of Draft Outcome Performance Measurement System for Community Planning and Development Formula Grant Programs; Request for Comments

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice.

SUMMARY: On September 3, 2003, HUD's Office of Community Planning and Development (CPD) issued CPD Notice 03–09 entitled, ''Development of State and Local Performance Measurements Systems for Community Planning and Development Formula Grant Programs.'' The notice encouraged CPD formula grantees that receive Community Development Block Grant (CDBG) Program, HOME Investment Partnerships Program (HOME), Emergency Shelter Grants (ESG), or the Housing Opportunities for Persons with AIDS Program (HOPWA) assistance to develop and use performance measurement systems. In March 2004, the Council of State Community Development Agencies (COSCDA) convened a meeting with representatives from the National Community Development Association (NCDA), the National Association for County Community Economic Development (NACCED), the National Association of Housing and Redevelopment Officials (NAHRO), the National Council of State Housing Agencies (NCSHA), CPD, HUD's Office of Policy Development and Research (PD&R), and the Office of Management and Budget (OMB) to discuss the development of a performance measurement system that would be used by CPD formula grantees to gather information and determine the effectiveness of their programs. That meeting resulted in the formation of a working group composed of representatives from those agencies and associations. The working group met at various times from June until November 2004 and developed the appendix entitled, ''Proposed Outcome Performance Measurement System'' which is attached to this notice. This notice solicits comments from the public and particularly from formula program grantees on the proposed performance measurement system.

DATES: *Comments Due Date:* September 8, 2005.

ADDRESSES: Interested persons are invited to submit comments regarding this notice to the Regulations Division, Office of General Counsel, Room 10276, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410–0500. Electronic comments may be submitted through either:

- The Federal Rulemaking Portal at *http://www.regulations.gov;* or
- The HUD electronic Web site at *http://www.epa.gov/feddocket.* Follow the link entitled, ''View Open HUD Dockets.'' Commenters should follow the instructions provided on that site to submit comments electronically.

Facsimile (FAX) comments are not acceptable. In all cases, communications must refer to the docket number and title. All comments and communications submitted will be available, without revision, for public inspection and copying between 8 a.m. and 5 p.m. weekdays at the above address. Due to security measures at the HUD Headquarters building, an advance appointment to review the public comments must be scheduled by calling the Regulations Division at (202) 708–3055 (this is not a toll-free number). Copies of the public comments are also available for inspection and downloading at *http://www.epa.gov/feddocket.*

FOR FURTHER INFORMATION CONTACT: Margy Coccodrilli, CPD Specialist, Office of Block Grant Assistance, Department of Housing and Urban Development, 451 Seventh Street, SW., Room 7282, Washington, DC 20410–7000, telephone, (202) 708–1577, extension 4507 (this is not a toll-free number). Hearing- or speech-impaired individuals may access this number through TTY by calling the toll-free Federal Information Relay Service at (800) 877–8339.

SUPPLEMENTARY INFORMATION:

I. Background

CPD Notice 03–09, ''Development of State and Local Performance Measurements Systems for Community Planning and Development Formula Grant Programs,'' encouraged grantees to develop state and local performance measurement systems. In addition, it described the need for HUD to begin to show the results of the federal dollars spent on the activities funded by the CDBG, HOME, ESG, and HOPWA programs.

Many CPD grantees have been frustrated by the inability to ''tell their story'' to their citizens and other stakeholders about the outcomes of the investments they have made in their communities using federal, state, and local resources. The inability to clearly demonstrate program results at the national level, which is the standard required by OMB's program assessment process, can have serious consequences on program budgets. The proposed outcome performance measurement system will enable HUD to collect information on the outcomes of activities funded with CPD formula grant assistance, and to aggregate that information at the national, state, and local level. The proposed outcome performance measurement system described by this notice is not intended to replace existing local performance measurement systems that are used to inform local planning and management decisions and increase public accountability. Grantees that had a local performance measurement system in place and those who are developing such a system should continue those efforts and are encouraged to make it compatible with this framework.

II. Performance Measurement Objectives

The proposed outcome performance measurement system has three overarching objectives: (1) Creating Suitable Living Environments, (2) Providing Decent Affordable Housing, and (3) Creating Economic Opportunities. There are also three outcomes under each objective: (1) Availability/Accessibility, (2) Affordability, and (3) Sustainability. Thus, the three objectives, each having three possible outcomes, will produce nine possible ''outcome/objective statements'' within which to categorize formula grant activities. Grantees will complete an outcome/objective statement in HUD's Integrated Disbursement and Information System (IDIS) by entering data in the form of an output indicator, seventeen of which have been specified and are described in the appendix to this notice.

Many of these output indicators already exist in IDIS for one or more formula programs, and this will be familiar to most grantees. However, HUD recognizes the need for terminology to be defined so that grantees, across programs, report data consistently. Some examples of terms that may require definition include numbers of persons served by public facilities or public services, area served, subsidized housing units, first-time homebuyers, and households served.

HUD requests that commenters pay special attention to the output indicators that are intended to represent most of the eligible activities carried out by grantees, and to offer definitions for

terms that may be subject to interpretation.

The list of indicators in the appendix does not attempt to describe the data collection process as it would appear in IDIS, but rather attempts to outline the fundamental IDIS data requirements across the four formula program areas and for each of the various eligible activities. In this document, the data output indicators are, by necessity, described in a narrative format that is repetitive. However, the performance measurement system will be incorporated into the redesign of IDIS, or any successor system, allowing for simplified data collection, including drop-lists and yielding performance data that can be aggregated and reported by HUD Headquarters, field offices, or grantees.

HUD acknowledges that there are some outcomes that the Department would like to be able to demonstrate that require more information than could be provided through the data described in this Notice. An example is determining whether a household that was assisted was able to maintain its homeownership. To minimize the burden on grantees, HUD will endeavor to undertake research and evaluation efforts to address such issues.

It is hoped that a fully redesigned IDIS would significantly reduce the overall administrative burden on grantees by folding the Consolidated Plan, Annual Action Plan, and Consolidated Annual Performance and Evaluation Report (CAPER) into a single performance measurement system, thereby eliminating duplicative data entries. In the interim, elements of the performance measurement system will be incorporated into the Consolidated Plan Management Process (CPMP) Tool so that local objectives and outcomes can be entered at the beginning of the Consolidated Plan or Annual Action Plan development process, and accomplishments under those objectives and outcomes can be reported in CAPER. Grantees should continue to encourage citizens and local organizations to participate in the development of their outcome-oriented performance measurement plans and reports and make drafts available for public comment via the Internet, where possible.

The first phase of the IDIS changes, which will be operational by late 2006 or early 2007, will include many elements of the proposed outcome performance measurement system. Consequently, the new performance measurement system is planned to be in place in time for reporting Fiscal Year (FY) 2007 program year activities. HUD intends to provide training in the first half of Calendar Year 2006 so that grantees can include the system's national objectives and outcome statements as part of their FY2007 Consolidated Plan or Annual Action Plan submission.

III. Additional Opportunities for Public Participation

HUD is actively soliciting comments from grantees to improve and fine-tune the design and actual use of this framework. CPD is also planning five facilitation sessions and one satellite broadcast to explain the importance of measuring performance and the use of the proposed outcome performance measurement system to capture those results. Dates and locations of the facilitation sessions are listed below. Additional information regarding the sessions can be obtained by accessing the following Web site: *http://www.icfhosting.com/hud/cdbg/registration.nsf* or by telephone, at (703) 934–3392.

Satellite Broadcast, June 30, 2005.

San Francisco, CA, July 18, 2005.

Philadelphia, PA, July 20, 2005.

Detroit, MI, July 26, 2005.

Atlanta, GA, July 28, 2005.

Austin, TX, August 2, 2005.

Persons wishing to comment, particularly program grantees, may use these sessions to do so, or may send comments directly to HUD using the contact information provided in the **ADDRESSES** section of this notice.

HUD intends to analyze the comments received and make any appropriate revisions prior to issuing final guidance. This will provide opportunity for grantees to include outcome measurements in their FY2007 Annual Action Plans.

Dated: June 7, 2005.

Pamela H. Patenaude,

Assistant Secretary for Community Planning and Development.

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APPENDIX

Proposed Outcome Performance Measurement System

A Working Group, established by and composed of representatives from national housing and community development associations, as well as HUD and the Office of Management and Budget (OMB), began holding monthly meetings in June 2004 for the purpose of developing an outcome performance measurement system for key HUD housing and community development programs. The working group was made up of grantee representatives from the Council of State Community Development Agencies, the National Community Development Association, the National Association for County Community Economic Development, the National Association of Housing and Redevelopment Officials, the National Council of State Housing Agencies, HUD's Offices of Community Planning and Development and Policy Development and Research and OMB.

On November 17 and 18, 2004, the members of this working group finalized their work and reached agreement on an outcome performance measurement system to propose for the CDBG, HOME, ESG, and HOPWA block grant programs. The proposed system includes objectives, outcome measures, and outcomes. The objectives are: Creating Suitable Living Environments, Providing Decent Affordable Housing, and Creating Economic Opportunities. The outcome categories are: Accessibility/Availability, Affordability and Sustainability. There is a specified list of output indicators that grantees would report on as appropriate for their chosen objectives and outcomes. Not all activities and funds are to be reported under this system, but the Working Group is confident that the list is broad enough so that results will be reported for a significant amount of activities for each program. Most of the output indicators required by the system do not require additional data collection or reporting.

As proposed, grantees would use this system in their five-year Consolidated Plans and Annual Action Plans, but are free to add objectives, outcomes, and indicators specific to their state or local initiatives or priorities. Modifications to existing HUD reporting requirements and mechanisms, such as IDIS, and CAPER or PER, will be made to include these outcomes, indicators, and appropriate data variables.

The system has been designed to enable grantees and HUD to inform Congress, OMB, and the public of many of the outcomes of the covered programs. The goal is to begin focusing on more outcome-oriented information and be able to aggregate results across the broad spectrum of programs at the city, county, and state level funded by these block grants.

HOW WILL IT WORK?

Based on their intent when funding an objective, grantees would determine under which of three objectives to report the outcomes of their projects and activities. Once the objective is chosen, the grantee would choose which of the three outcome categories best reflects what they are seeking to achieve (the results) in funding a particular activity. Next, grantees would choose

from a list of indicators (also known as outputs) to report on, and supply the data for those indicators to HUD.

The system maintains the flexibility of the block grants programs as the objectives are determined by the grantees based on the intent of the project and activity. While program flexibility is maintained, the system offers a specific menu of objectives, outcomes, and indicators so that reporting can be standardized, and the achievements of these programs can be aggregated to the national, state, and local level.

OBJECTIVES

Suitable Living Environment. In general, this objective relates to activities that are designed to benefit communities, families, or individuals by addressing issues in their living environment.

Decent Affordable Housing. The activities that typically would be found under this objective are designed to cover the wide range of housing possible under HOME, CDBG, HOPWA, or ESG. This objective focuses on housing programs where the purpose of the program is to meet individual family or community needs and not programs where housing is an element of a larger effort (such as would be captured above under Suitable Living Environment).

Creating Economic Opportunities. This objective applies to the types of activities related to economic development, commercial revitalization, or job creation.

OUTCOMES

Availability/Accessibility. This outcome category applies to activities that make services, infrastructure, housing, or shelter available or accessible to low- and moderate-income people, including persons with disabilities. In this category, accessibility does not refer only to physical barriers, but also to making the affordable basics of daily living available and accessible to low- and moderate- income people.

Affordability. This outcome category applies to activities that provide affordability in a variety of ways in the lives of low- and moderate-income people. It can include the creation or maintenance of affordable housing, basic infrastructure hook-ups, or services such as transportation or day care.

Sustainability: Promoting Livable or Viable Communities. This outcome applies to projects where the activity or activities are aimed at improving communities or neighborhoods, helping to make them livable or viable by providing benefit to persons of low- and moderate-income people or by removing or eliminating slums or blighted areas, through multiple activities or services that sustain communities or neighborhoods.

OUTPUT INDICATORS

Although implementation of the system has not yet been designed, the belief of the Working Group is that most of the input of data on output indicators will be accomplished by a

menu-driven "pick list." While there are some data or outputs that will be required for each activity, for the most part grantees will be required to report only on the indicators that apply to the activity funded and source of funds (CDBG, HOME, HOPWA or ESG). If there is an indicator that is not applicable to the activity or an existing program requirement (statutory or regulatory), then reporting is not required for that indicator. However, if such information is available, grantees are encouraged to report that information so that the most accurate numbers can be aggregated.

For each activity, grantees would report on:

- Amount of money leveraged (from other federal, state, local, and private sources) per activity;
- Number of persons, households, units assisted (pick the one most appropriate to project or activity, one only);
- Income levels of persons or households by 30%, 50%, 60%, or 80% of area median income, per applicable program requirements (area benefit activities will show the total number of persons served and the percentage of low- and moderate- income persons served). However, this requirement is not applicable for economic development projects awarding funding on a "made available basis;"
- Number of communities/neighborhoods assisted; and
- Race, ethnicity, and disability (current categories for beneficiary reporting still apply).

Specific Indicators (for CDBG, HOME, ESG, and HOPWA, if applicable)

1) If Activity is _____(select from the list of infrastructure and public service activities)

Number of households assisted:

- with new access to service or benefit
- with improved access to service or benefit
- where activity was used to meet a quality standard or measurably improved quality, report number of households that no longer have access to substandard service only

2) Activities are part of a geographically targeted revitalization effort (Y/N)?

If Yes (check one)

a) Comprehensive
b) Commercial
c) Housing
d) Other

Choose all the indicators that apply, or at least 3 indicators if the effort is (a) Comprehensive.

- Number of new businesses assisted
- Number of businesses retained
- Number of jobs created or retained in target area
- Amount of money leveraged (from other public or private sources)

- Number of LMI persons served
- Slum/blight demolition
- Number of LMI households assisted
- Number of acres of remediated brownfields
- Number of households with new or improved access to public facilities/services
- Number of commercial façade treatment/business building rehabilitations
- Other – can include: crime numbers, property value change, housing code violations, business occupancy rates, employment rates, homeownership rates (optional)

3) Does activity address slum and blight spot basis (Y/N)?

4) Number of commercial façade treatment/business building rehabilitations (site, not target area based)

5) Number acres of brownfields redeveloped (site, not target area-based)

6) Number of rental units constructed (new) per project or activity

Total number of units:
Of total:
Number affordable
Number Section 504 accessible

Of affordable:
Number subsidized by program (federal, state, or local, with pick list to specify which federal program)
Number of years of affordability guaranteed
Number of housing units (supported through development and operations or rental assistance) for persons with HIV/AIDS:
Of those, number of units for the chronically homeless
Of those, the number made Section 504-accessible
Number of units of permanent housing for homeless persons and families (supported through development and operations):
Of those, number of units for the chronically homeless
Of those, the number made Section 504-accessible

7) Number of rental units rehabilitated

Total Number of units
Of total:
Number Affordable
Number Section 504-accessible
Number brought from substandard to standard condition (HQS or local code)
Number meeting International Building Code (IBC) Energy standards
Of those, number meeting Energy Star standards
Number brought into compliance with lead safe housing rule (24 CFR part 35)

Of Affordable:

Number subsidized by federal, state, or local program (with pick list to specify which federal program)

Number subsidized by program

Number of years of affordability guaranteed

Number of housing units (supported through development and operations) for persons with HIV/AIDS

Of those, the number of units for the chronically homeless

Of those, the number made Section 504-accessible

Number of units of permanent housing for homeless persons and families (that are supported through development and operations)

Of those, number of units for the chronically homeless

Of those, the number made Section 504-accessible

8) Number of owner occupied units rehabilitated or improved

Number of units brought from substandard to standard condition (HQS or local code)

Number of units brought to International Building Code Energy standards

Of those, number brought to Energy Star standards

Number of units brought into compliance with lead safe housing rule (24 CFR part 35)

Number of units subsidized by federal, state or local program (pick list to specify which federal program)

Note: Owner-occupied units are not subject to Section 504 compliance

9) Direct Financial Assistance to homebuyers (Choose all that apply)

First-time homebuyers: Y/N

Subsidized tenants: Y/N

Minority household: Y/N

Downpayment Assistance: Y/N

Closing Costs: Y/N

Mortgage buy-down/Reduction: Y/N

Interest Reduction: Y/N

Second Mortgage: Y/N

10) Number of jobs created

Employer-sponsored health care benefits: Y/N

Type of jobs created (use existing Economic Development Administration (EDA) classification)

Employment status before taking job created:

Number of unemployed _____(N/A for projects awarding funding on a "made available to" basis.)

11) Number of jobs retained, saved, or maintained

Employer-sponsored health care benefits: Y/N
Type of job created (use existing EDA classification)
Prior employment status before taking job created:
Number of unemployed _____(N/A for projects awarding funding on a "made available to" basis)

12) Number of businesses assisted:

- New
- Expansions
- Relocations

DUNS number(s) of those businesses
Two-digit NAIC industry classification (if needed w/ DUNS)

13) Number of new businesses that remain operational 3 years after assistance.
(no reporting necessary, HUD to determine through DUNS report)

14) Does assisted business provide a good or service to meet needs of service area/neighborhood/community (to be determined by community)? Y/N

15) Number of Homeownership Units Constructed, Acquired, and/or Acquired with Rehabilitation (per project or activity)

Total Number of Units

Of those:
Number of affordable units
Number of years affordability guaranteed
Number meeting International Building Code Energy standards
Of those, the number using Energy Star standards
Of those, the number made Section 504-accessible

Of affordable:
Number subsidized by state/local programs
Number subsidized by federal programs
Number specifically for persons with HIV/AIDS
Number specifically for homeless
Of those, number specifically for chronically homeless
Of those, the number made Section 504 accessible

16) Number of renter units assisted with ongoing (monthly) subsidies (Tenant-based Rental Assistance)

Total Number of Units

Of those:
Number subsidized by state/local programs
Number subsidized by federal programs
Number assisting persons with HIV/AIDS
Number assisting homeless
Of those, number assisting chronically homeless
Of those, the number made Section 504-accessible

17) Number of homeless persons stabilized due to access to overnight shelter or other emergency housing support

Examples

Each outcome category can be connected to each of the overarching objectives, resulting in a total of nine groups of outcome/objective statements under which grantees would report the activity or project data to document the results of their activities or projects. They are activities or projects that provide:

- Accessibility for the purpose of creating suitable living environments
- Accessibility for the purpose of providing decent affordable housing
- Accessibility for the purpose of creating economic opportunities
- Affordability for the purpose of creating suitable living environments
- Affordability for the purpose of providing decent affordable housing
- Affordability for the purpose of creating economic opportunities
- Sustainability for the purpose of creating suitable living environments
- Sustainability for the purpose of providing decent affordable housing
- Sustainability for the purpose of creating economic opportunity

Each output should relate to the intended outcome/objective of the program activities and community objectives. A complete statement has these components: Output (quantified) + Outcome (from categories above) + Activity (description) + Objective. Combining these elements into a single sentence summarizes the community's activities, results, intended outcomes, and purpose in a way that can be related to resource inputs. Sometimes an adjective such as new, improved, or corrective may be appropriate to refine the outcome statement.

- 2000 homeless persons have new access to a shelter for the purpose of creating decent affordable housing
- 7 households have new access to homeownership for the purpose of creating decent affordable housing
- 24 households have sustained affordable housing by emergency repair for the purpose of providing decent affordable housing
- 52 households have new access to public sewer for the purpose of creating a suitable living environment
- 52 households have affordable public sewer for the purpose of creating a suitable living environment
- 50 persons have access to new jobs through extension of a water line to a business for the purpose of creating economic opportunity
- 50 households have affordable housing through a down payment assistance program for the purpose of creating decent affordable housing
- 75 very low-income persons living with HIV/AIDS were assisted with on-going (monthly) housing subsidies for the purpose of providing decent affordable housing

These would be the type of outcome statements grantees would report to HUD and include in their Consolidated Plans and Annual Action Plans. See diagram.

PERFORMANCE OUTCOME MEASUREMENT SYSTEM

Step 1: Assess Needs and Select Goals

Step 2: Select Objectives with Outcomes

Availability/Accessibility	Affordability	Sustainability
Enhance Suitable Living Environment Through New/Improved Accessibility	Enhance Suitable Living Environment Through New/Improved Affordability	Enhance Suitable Living Environment Through New/Improved Sustainability
Create Decent Housing with New/Improved Availability	Create Decent Housing with New/Improved Affordability	Create Decent Housing with New/Improved Sustainability
Promote Economic Opportunity Through New/Improved Sustainability	Provide Economic Opportunity Through New/Improved Affordability	Provide Economic Opportunity Through New/Improved Sustainability

Step 3: Design Programs and Choose Activities

Housing Rehabilitation	HIV/AIDS Housing	Housing Counseling
Rental Housing Production	Tenant-based Rental Assistance	Public Services
Community Facilities	Economic Development	Code Enforcement
Public Safety	Housing for Homeless	Water/Sewer
Infrastructure	Special Needs Housing	Utilities
Lead-based Paint Activities	Homeownership Assistance	Transportation

Step 4: Complete the Consolidated Plan/Action Plan

Step 5: Develop the Outcome Statement

Output (quantified) + Outcome + Activity (description) + Objective

Choose indicators based on activity and outcome: (examples)

Number of households assisted	Number of persons stabilized
Number of new businesses assisted	Acres of brownfields remediated
Number of jobs created/retained	Amount of money leveraged
Number of units made 504-accessible	Number of affordable units
Number of years of affordability guaranteed	Number of housing units for HIV/AIDS
Number of jobs with health care benefits	Number of units for chronically homeless
Number of units meeting Energy Star standards	Number of units made lead safe

Step 6: Report (IDIS, CAPER, PER)

For all projects report program requirements plus:

Income levels of persons, or households (30%, 50%, 60%, or 80% of area median income)

Leverage	Number of persons, households, units
Number of communities/neighborhoods assisted	Current racial/ethnic and disability categories

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This is a continuing list of public bills from the current session of Congress which have become Federal laws. It may be used in conjunction with "P L U S" (Public Laws Update Service) on 202–741–6043. This list is also available online at *http://www.archives.gov/federal_register/public_laws/public_laws.html*.

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Surface Transportation Extension Act of 2005 (May 31, 2005; 119 Stat. 324)

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